

June 25, 2013

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-1599-P: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems (IPPS) for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Fiscal Year (FY) 2014 Rates

Dear Ms. Tavenner,

America's Essential Hospitals, formerly the National Association of Public Hospitals and Health Systems (NAPH), appreciates the opportunity to submit comments on the above-captioned proposed rule. America's Essential Hospitals thanks the Centers for Medicare & Medicaid Services (CMS) for working to develop incentives that promote high-quality care. We support efforts to improve care among our membership and across the entire health care industry. However, certain proposals will have a disproportionate negative financial impact on essential hospitals due to the patient populations they serve. To this end, America's Essential Hospitals asks CMS to consider the unique challenges inherent in caring for our nation's most vulnerable patient populations when finalizing this rule.

America's Essential Hospitals represents more than 200 hospitals that are vital to their communities, providing primary care, trauma care, disaster response, health professionals training, research, public health programs, and other services. They innovate and adapt to lead the broader health care community toward more effective and efficient care. These organizations constitute just 2 percent of acute care hospitals nationwide but provide 20 percent of all hospital uncompensated care. Our members predominantly serve patients covered by public programs and the uninsured—25 percent

of the inpatient services provided by our members are to Medicare beneficiaries, another 36 percent are to Medicaid recipients, and 18 percent are to uninsured patients. As essential community providers, 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 looming cuts in the Affordable Care Act (ACA) and other hospital cuts that Congress has targeted to offset federal spending.

To ensure our members have sufficient resources to continue to engage in robust quality improvement 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 DSH payments.

As part of the proposed rule, CMS details how it will implement the ACA's changes to Medicare DSH payments. The Medicare DSH program provides essential financing for the uncompensated care (UC) provided by members of America's Essential Hospitals. In 2010, 16 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 (a level CMS refers to as the "empirically justified amount"), the remaining 75 percent of Medicare DSH payments will be adjusted to reflect the change in the national uninsurance rate and distributed based on UC (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 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 fulfill a safety net role and the vulnerable patients they serve, particularly with respect to how the agency defines UC for purposes of implementing factor 3 of the ACA's Medicare DSH provision, which allocates the UC-based Medicare DSH payments among eligible hospitals. CMS should continue to work on accurately capturing UC costs—during transition periods and as circumstances and data sources evolve. CMS should make transition periods as short

as possible and aid the process with clarifications to the Medicare cost report and other guidance, so Medicare DSH payments are targeted to the hospitals that need them most, thus fulfilling Congress' intent to capture UC costs.

Below are specific comments of particular importance to our member hospitals.

a. CMS should increase its estimate of total Medicare DSH payments it would otherwise make without regard to the ACA's Medicare DSH provision for FY 2014.

CMS should ensure its estimate of the total amount of Medicare DSH payments it would otherwise make in FY 2014 is correct. Since publishing the proposed rule, CMS released the assumptions used to come up with the amount of Medicare DSH payments the agency would otherwise make. These assumptions include the proposed documentation and coding adjustment. However, rather than reflecting the proposed adjustment factor of -0.8 percent, the assumptions indicate that CMS incorporated a -2.0 percent adjustment. Our analysis indicates the amount of Medicare DSH payments that would be made should be at least \$12.49 billion, rather than the \$12.34 billion as noted in the proposed rule. Because CMS has proposed to determine the UC-based Medicare DSH payments prospectively, without reconciling the amount based on actual utilization, it is critically important for CMS to start with an accurate estimate of total Medicare DSH payments for the year. An incorrect estimate will lead to less support for our hospitals and other hospitals with high amounts of UC. For these reasons, CMS should ensure its estimate of total Medicare DSH payments it would otherwise make for FY 2014 is correct.

b. CMS should finalize its proposal to use 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. In order to estimate the decline in the national uninsurance rate, CMS proposes 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, but finalizing

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¹The ACA specifies that the uninsurance rate 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" (CBO) from immediately prior to the ACA's passage. The requirement that the secretary "calculate" the rate indicates she is to do more than simply use the CBO estimates issued in 2010. 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

this aspect of the proposal would also ensure an adequate level of Medicare DSH resources remain available to high UC hospitals. **Therefore, CMS should finalize this proposal.**

c. CMS should continue its work to accurately capture hospital UC costs in its calculation of factor 3 of the Medicare DSH methodology.

In the proposed rule, CMS concludes that due to shortcomings with data from the Medicare cost report, 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 use a hospital's Medicaid days plus Medicare supplemental security income (SSI) days as the proxy. CMS notes the proxy is an interim measure and proposes to continue to monitor alternative proxies and data sources. We have 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. We also were strong supporters of Congress' directive to CMS in the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 to collect data on hospital UC, with the intent that such data could be factored into the Medicare DSH formula—which resulted in the establishment of worksheet S-10.2 Given the importance of UC to the ACA-revised Medicare DSH program, we urge CMS to continue to refine factor 3 to accurately capture UC costs. Specifically, CMS should consider the following refinements to the Medicare cost report worksheet S-10 so the data captured on the worksheet can be used for the Medicare DSH program.

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:

as the 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."

²BBRA, H.R. 3426, § 112(b) (1999), enacted by reference in Pub. L. 106-113, 113 Stat. 1501, Div. B, § 1000(a)(6) (1999).

- 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 UC. In addition to employing physicians and paying community specialists directly for providing care to patients, many of our member 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 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. 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 they report charity care versus bad debt.

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 20.³ However, hospitals often determine and write off charity care outside of the FY in which services are provided. 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. Therefore, CMS should revise its instructions to ensure all charity care is captured.

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.

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³Medicare Provider Reimbursement Manual, Part 2, Provider Cost Reporting Forms and Instructions, Form CMS 2552-10S-10 Instructions, § 4012.

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 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 distorts shortfall amounts. 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 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 versus actual 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 consider additional implications when evaluating its proposed UC proxy.

As CMS evaluates alternatives or modifications to its proposed 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 variation in the amount of resources required to treat certain patients.

These considerations further highlight the need to capture accurate UC data so that CMS can refine its Medicare DSH methodology and distribute UC-based Medicare

DSH payments using UC data. 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 days so that the data used to compare hospitals capture the disproportionate nature of each hospital's commitment to low-income populations.

d. CMS should ensure the full amount of Medicare DSH payments under the ACA methodology is accounted for in other Medicare payments.

CMS notes in the preamble of the proposed rule that only the empirically justified DSH amount will be included in the prospective payment system pricer, which many Medicare Advantage (MA) plans use to pay hospitals. As support for this position, CMS reasons that only this portion of Medicare DSH payments will continue to be paid on a perdischarge basis. As a result of this decision, providers that contract with MA plans for the "Medicare rate" would see lower payments. The UC-based Medicare DSH payment is still a Medicare payment for services.⁴ Providers should not be compensated less for services provided to patients enrolled in MA rather than traditional Medicare—particularly where there is an existing model for a technical fix to address the issue.

We urge CMS to address this problem by adding the UC-based DSH payments to the pricer as a non-pay item for patients enrolled in MA similar to the agency's treatment of operating indirect medical education payments (O-IME). In the current pricer, hospitals check a box to identify whether a claim is paid under Medicare Part A or is a health maintenance organization (HMO) paid claim under Part C. If the HMO paid claim box is checked, the pricer excludes the O-IME portion of the payment from the total amount that is calculated for the total operating amount. Thus, we suggest that CMS add a line to the pricer, immediately below the operating DSH line, to show the per claim value of the UC-based DSH payments which are being paid to the hospital as interim payments. CMS would calculate the per claim amount to be included in the pricer so that it is equivalent to the total periodic interim payments to be paid to a hospital based on the agency's estimate of the number of discharges for each hospital for the FY. We believe that this suggestion, coupled with guidance from CMS, would assist MA plans in making appropriate payments to hospitals reflecting the full amount of the Medicare DSH payment. CMS has provided MA plans with guidance on how to exclude certain components of the pricer from hospital payment and the agency should provide comparable guidance on how to include certain components in hospital payment when those components are modified, such as the Medicare DSH components under the ACA.

Finally, we note that our request to change the pricer is not asking CMS to take an extraordinary action. The agency frequently makes changes to the pricer, as it did recently to incorporate other new payment policies established by the ACA – i.e., the

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⁴Section 3133 of the ACA added the UC portion of the DSH payment to Section 1886 (specifically, 1886(r)) of the Social Security Act, "Payment to Hospitals for Inpatient Hospital Services."

value-based purchasing and the readmissions reduction programs. Therefore, CMS should ensure the full amount of Medicare DSH payments under the ACA methodology is included in the PPS pricer.

e. CMS should distribute the additional UC portion of the Medicare DSH payments as frequently as possible.

CMS proposes to make the UC-based Medicare DSH payments on a periodic basis. However, CMS should specify in the final rule how and when these payments will be made. In doing so, the agency should carefully consider the impact of timing on hospitals' cash flow and operations and implement the changes to the Medicare DSH formula in a way that does not disrupt hospitals' ability to provide care to patients. Specifically, CMS should make these payments on a biweekly basis, consistent with its methodology for making Medicare bad debt payments. For those hospitals determined eligible only during the reconciliation process, CMS should make the payments as soon as possible and specify the time frame in the final rule.

2. CMS should continue to refine its medical review criteria and payment policy with regard to inpatient services so hospitals receive appropriate reimbursement for stays that should be classified as inpatient admissions.

CMS should revise its medical review criteria and payment policy with regard to inpatient services so hospitals are properly reimbursed for inpatient admissions ordered by physicians using informed clinical judgment. CMS proposes to revise the process through which Medicare review contractors evaluate inpatient hospital admissions for Medicare Part A payments. This policy change is intended to address the increase in the use of outpatient observation services to care for Medicare beneficiaries by shifting some of these longer stays in observation status to inpatient admissions. Physicians and hospitals have become reluctant to admit Medicare beneficiaries as inpatients because a review contractor may possibly overturn a physician's clinical decision after the fact. In such cases the hospital would not be paid under Medicare Part A, and until recently, could not rebill the stay for outpatient reimbursement under Medicare Part B.

CMS proposes to codify its existing policy on the definition of an inpatient admission by adding a section to the payment regulations that will define an inpatient as an individual who is formally admitted as an inpatient based on a physician order. CMS also proposes to include a presumption that an inpatient admission supported by a physician order is reasonable and necessary when the stay lasts for more than one Medicare utilization day, which means the patient's stay crosses two midnights. Under CMS' existing policy, a review contractor evaluates an inpatient admission to ensure there was a physician order requesting the admission and that it was medically necessary based on the contractor's review of the medical record. CMS estimates that due to the proposed changes to the inpatient admission criteria, more stays will be classified as inpatient admissions. This

increases IPPS payments made to hospitals by an estimated \$220 million. CMS chooses to offset this increase by reducing the standardized amount by 0.2 percent.

a. CMS should not reduce hospital payments to offset expected increases in IPPS expenditures due to the proposed changes in medical review criteria.

CMS should not make a payment adjustment to offset its expected increase in inpatient payments due to the proposed changes in medical review criteria. All hospitals paid under IPPS would be subject to these across-the-board cuts. CMS should not require hospitals to shoulder the burden for this policy. CMS cites the secretary's authority under the Social Security Act to offset the additional expenditures with cuts. But, the proposed change is a CMS policy decision to attempt to clarify its existing medical review criteria, which is deeply flawed and gives review contractors unrestrained authority. The inpatient admissions that would stem from the change in criteria will be based on qualified physicians' clinical decisions, and hospitals should receive compensation for these inpatient admissions without being subjected to a cut. In fact, hospitals currently should be reimbursed under Medicare Part A for these types of admissions but are frequently being denied under the existing medical review criteria.

America's Essential Hospitals is concerned that our member hospitals will see payment cuts that are detrimental to their already low operating margins. Already facing cuts made through other programs, our hospitals will have increased difficulty fulfilling their mission to provide quality care to all patients, regardless of their ability to pay. To ensure hospitals receive appropriate funding for their inpatient admissions, and are not subjected to subsequent payment cuts, CMS should not make the proposed payment reductions to pay for what the agency thinks will be increased expenditures.

b. CMS should limit the excessive authority of Medicare review contractors when reviewing inpatient admissions lasting more than one Medicare utilization day.

CMS should allow Medicare review contractors to review inpatient admissions that last for more than one Medicare utilization day only in limited instances when there is a clear indication of fraud or abuse. Under CMS' proposed policy, a review contractor would presume that a stay that was ordered by a physician and surpasses two midnights was medically necessary and therefore qualifies for Medicare inpatient reimbursement. Although there is a presumption that the inpatient admission is reasonable and necessary when it spans at least two midnights, the contractor still maintains the authority to review the entire medical record in a case and reverse a physician's judgment, even where there is a physician order and certification. Specifically, CMS notes that review contractors still should evaluate all inpatient admission decisions to identify any stays that were inappropriately prolonged to meet the two midnight requirement. Also, a physician's order would hold no presumptive weight regarding the medical necessity of an inpatient admission and would be evaluated in conjunction with the evidence in the medical record.

While the proposed policy provides more clarity by adding the length of stay element to the criteria for an inpatient admission, the Medicare review contractor still retains excessive authority to make decisions that contradict the clinical judgment of a licensed physician who issued a physician order. These decisions by review contractors, which are frequently erroneous and reversed on appeal, can result in hospitals not being appropriately reimbursed for inpatient admissions in cases where the physician's initial judgment was correct. For safety net hospitals already stretched thin, these inappropriate and inaccurate reviews are truly detrimental. Therefore, in cases where there is no indication of fraud or abuse, CMS should remove this excessive review authority and consider stays lasting more than one Medicare utilization day (i.e., crossing two midnights) reasonable and necessary inpatient admissions.

c. CMS also 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 after 72 hours of observation services and pay hospitals a DRG payment for these "deemed-admitted" patients. Hospitals provide observational 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. 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 coverage so the period of observation care is counted toward meeting the 3-day requirement for patients who are subsequently admitted to the hospital, including these "deemed-admitted" patients. For these reasons, CMS should deem patients under observation status to have been admitted for inpatient payment purposes after 72 hours.

3. 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 include additional 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 also include appropriate risk-adjustment methodology. America's Essential Hospitals has previously expressed concern that the 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.

Our member hospitals' average margin is 2.3 percent, compared to 7.2 percent for hospitals nationally. Based on the floor adjustment factors established by the ACA, hospitals face up to a 2 percent payment reduction in FY 2014 and a 3 percent reduction beginning in FY 2015. If the necessary adjustments are not made to accurately measure readmissions, our members could face devastating cuts to their operating margins. Given their already low operating margins, cuts to their base operating DRG payments could have a profound impact on essential hospitals and their ability to provide care to our nation's most vulnerable patients.

a. CMS should adopt the proposed updated algorithm for identifying planned readmissions because it is an improvement over the existing program.

CMS should adopt the proposed updated readmissions algorithm, which would exclude certain planned readmissions from being counted when calculating a hospital's readmissions adjustment factor. CMS proposes to expand its definition of planned readmissions, for the three conditions already included, as well as the two proposed conditions. The updated methodology would classify a wider range of readmissions as planned readmissions, excluding them from being counted against a hospital. Under the proposed algorithm, certain types of services are always considered planned and thus not counted against a hospital, namely obstetrical delivery, transplant surgery, maintenance chemotherapy, and rehabilitation. Nonacute readmissions for scheduled procedures are also classified as planned readmissions and therefore not included in a hospital's readmissions calculation. And finally, unplanned readmissions that take place after a planned readmission would not count as a readmission. Modifying the readmissions measures to exclude certain types of readmissions is a positive step toward ensuring a hospital's reimbursements are not reduced for appropriate readmissions to the hospital. For this reason, CMS should finalize this proposal.

b. <u>CMS should include risk-adjustment methodology for the existing and proposed</u> 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

⁵Obaid Zaman, L. Cummings, and S. Laycox, "America's Safety Net Hospitals and Health Systems, 2010: Results of the Annual NAPH

Hospital Characteristics Survey," National Association of Public Hospitals and Health Systems, May 2012, http://www.naph.org/Main-Menu-

Category/Publications/Safety-Net-Financing/2010-NAPH-Characteristics-Report.aspx?FT=.pdf

based on three applicable conditions: acute myocardial infarction (AMI), heart failure (HF), and pneumonia (PN). CMS proposes to include two new conditions beginning in FY 2015—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 the two proposed readmission measures is the same as that used in calculating the AMI, HF, and PN measures—it does not incorporate appropriate risk-adjustment that accounts for race, socioeconomic status, language, insurance status, post-discharge support structure, or other factors that reflect the unique difficulties involved in providing care to vulnerable populations.

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.⁶ 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 measures, such as including adequate risk-adjustment, that would also mitigate the disproportionate effects of the program.

America's Essential Hospitals urges CMS to include factors relating to a patient's background—socioeconomic status, languages spoken, insurance status, post-discharge support structure, and race—in its risk-adjustment methodology. These underlying factors—as opposed to the quality of care provided—frequently drive readmissions to our hospitals. And recent studies have shown that readmissions are not necessarily a reliable indicator of the quality of care the hospital provides, placing excessive emphasis on readmissions rates can result in the misallocation of hospitals' already scarce resources.⁷

Hospitals with low readmissions rates but high mortality rates, for example, would receive lower 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. 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. America's Essential Hospitals previously noted that CMS' Hospital Compare data illustrate that hospitals providing

⁶MedPAC Report to Congress, Medicare and the Health Care Delivery System, June 2013.

⁷Karen E. Joynt and A. K. Jha, "A Path Forward on Medicare Readmissions," *New England Journal of Medicine* 368, no. 13 (2013): 1175-77.

⁸Ibid.

⁹ MedPAC Report to Congress, Medicare and the Health Care Delivery System, June 2013.

care to vulnerable populations are achieving lower mortality rates than the national average while patients are in the hospital. 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.

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 fact, the FY 2013 program has already disproportionately penalized many of the nation's essential 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. And teaching hospitals and large hospitals, both of which tend to provide care to vulnerable populations, more often face higher penalties. Adding additional measures to the readmissions reduction program without first addressing the inadequacies in the existing methodology would even more negatively impact essential hospitals and the vulnerable populations they treat. For these reasons, CMS should include a sufficient riskadjustment methodology in the readmissions reduction program.

c. CMS should not add the COPD condition to the readmissions reduction program for FY 2015.

While CMS proposes to add COPD to the readmissions reduction program in FY 2015, CMS proposes to include the COPD measure to the hospital inpatient quality reporting (IQR) program a year later. Beginning in FY 2016, CMS proposes to include the 30-day, all-cause, risk-standardized readmission rate (RSRR) following COPD hospitalization as one of the measures in the hospital IQR program. CMS should not include this measure in the readmissions reduction program before it has been in the IQR program for at least 2 years to allow hospitals the opportunity to report these readmissions through the IQR program and improve their performance on this measure before they face the prospect of being penalized through the readmissions reduction program. CMS should ensure hospitals have a chance to improve on this condition in the IQR program first, before including it in the readmissions reduction program or other pay-for-performance programs. Hospitals need the opportunity to demonstrate progress on the COPD measures prior to facing monetary penalties for their performance on them. Therefore, CMS should ensure the COPD readmissions measure is included in the IQR program for at least 2 years before adding this measure to other quality improvement programs. In addition, CMS should use this time to further assess the

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 ¹⁰Karen E. Joynt and A. K. Jha, "Characteristics of Hospitals Receiving Penalties Under the Hospital Readmissions Reduction Program," *Journal of the American Medical Association* 309, no. 4 (2013): 342-43.
 ¹¹Ibid.

measure and ensure its reliability is robust enough to use in the readmissions reduction program.

The chronic and progressive nature of COPD, as well as the environmental factors associated with its development, could result in an increase in a hospital's readmission penalty—in particular for hospitals filling a safety net role. The types of readmissions associated with COPD patients are often not related to the quality of care hospitals provide during the initial admission but are instead caused by external factors.

COPD is characterized by obstruction of the respiratory tract, difficulty breathing, and inflammation of the airways. It is most often caused by smoking, with up to 90 percent of cases attributed to tobacco smoke exposure. Environmental factors, such as occupational hazards and air pollution, are also risk factors for COPD. Vulnerable populations, including racial and socioeconomic minorities, are at greater risk of developing COPD because of their exposure to these types of external factors. For example, racial and socioeconomic minorities tend to be concentrated in large cities, which typically have greater air pollution. These populations also have increased exposure to occupational risk factors, and African Americans in particular have a higher rate of smoking. Given these vulnerable populations frequently seek care at our member hospitals, the likelihood of our hospitals admitting patients for the COPD condition is greater. If these patients are subsequently readmitted for any cause not classified as a planned readmission, our members will face undue penalties.

Due to the all-cause readmission standard, as well as the fact that vulnerable populations are often readmitted for complications arising from their lack of a post-discharge support structure, including COPD as an applicable condition may unfairly affect our member hospitals. Individuals with COPD are predisposed to other respiratory conditions, such as spontaneous pneumothorax, a condition characterized by lung collapse and breathlessness. These types of conditions are not the result of poor quality of care for the original COPD admission but would inevitably require a patient to be readmitted. Penalizing a hospital for subsequent readmissions does not take into account the complexities surrounding the COPD condition and the prevalence of these types of illnesses in patients prone to the COPD condition. Including the COPD condition in the readmissions program could result in a hospital being held accountable for conditions that arise within 30 days of the index admission but that were not foreseeable, preventable, or associated with the quality of care the hospital initially provided.

¹²Marvin Dewar, MD, JD, and R. Whit Curry, Jr., MD, "Chronic Obstructive Pulmonary Disease: Diagnostic Considerations," *American Family Physician* 73, no. 4 (2006): 669-76.

¹³Ibid.

 ¹⁴Mark Eisner, et al., "Socioeconomic Status, Race, and COPD Health Outcomes,"
 Journal of Epidemiology and Community Health 65, no. 1 (2004): 26-34.
 ¹⁵Kaiser Family Foundation, Percent of Adults who Smoke by Race/Ethnicity, available at

Therefore, including the COPD condition would penalize hospitals for readmissions that are not caused by poor quality of care. For these reasons, CMS should not include the COPD condition in the readmissions reduction program for FY 2015.

d. CMS should alter the readmissions calculation so readmissions unrelated to the index admission do not count against a hospital.

CMS should adopt exclusions for readmissions unrelated to the index admission. such as subsequent unrelated hospitalizations for trauma and burn care, mental illness or substance abuse, and end-stage renal disease. By adopting additional exclusions for readmissions unrelated to the index admission, CMS will fulfill the statutory language of the ACA, which specifically requires the readmissions measures to exclude unrelated readmissions. In addition to using an all-cause readmissions standard for the three existing conditions, CMS proposes an all-cause readmissions standard for the two new conditions. While the planned readmissions algorithm would reduce the number of readmissions that count toward excess readmissions, the algorithm still does not account for unplanned readmissions unrelated to the index admission. Patients at safety net hospitals are often likely to be readmitted due to socioeconomic factors, including homelessness and lack of a sufficient post-discharge support structure. Our hospitals should not be penalized for readmitting these patients for reasons unrelated to the quality of initial care provided. Many of our hospitals operate trauma centers and provide treatment for trauma and burn victims. These hospitals should not be penalized for admitting patients who need essential care that often cannot be found elsewhere in the community and is completely unrelated to the cause of the index admission. For these reasons, CMS should exclude unrelated readmissions from being counted against a hospital.

e. <u>CMS</u> should change the exclusion for transfers so the capabilities of and amount of care provided by the transferring hospital are taken into account before <u>CMS</u> attributes the index admission to the hospital receiving the transfer.

CMS should alter its definition of transfers to account for the amount of care provided at the transferring hospital, so the receiving hospital is not penalized for future readmissions that may not be the result of care provided at that hospital. When defining "transfers," for both the existing and the proposed conditions, CMS applies an exclusion to the hospital initiating the transfer and attaches the index admission to the hospital receiving the transfer and ultimately discharging the patient to a nonacute setting. In cases where a hospital transfers a patient to another hospital for legitimate reasons, such as a lack of resources to provide the specialized care necessary to the patient, the current readmissions transfer policy may be appropriate. But in instances where the transferring hospital had significant interaction with and provided appropriate care to a patient, the index readmission should not necessarily be associated with the hospital receiving the transfer. A complication that arises within 30 days that requires a readmission may be the result of the initial care provided at the transferring hospital as opposed to the care subsequently provided at the receiving hospital.

Additionally, in some cases the transferring hospital is able to provide specialized care but transfers the patient for reasons such as the patient's lack of health insurance. Attaching the index admission to the receiving hospital could encourage capable hospitals to transfer patients once they have fulfilled their obligation to provide the basic services necessary and discourage other hospitals from accepting these transfers—an undesirable outcome in terms of patient care. Hospitals that fulfill a safety net role frequently accept patient transfers from other hospitals due to their mission to provide treatment to all patients, and the readmissions transfer policy as it is currently proposed would be detrimental to these hospitals and the care they provide to vulnerable populations. These hospitals will likely see a greater number of readmissions that have no association with the quality of care they provided during their initial contact with the patient. For these reasons, CMS should modify the definition of the transfer exclusion in the readmissions program to take into account the level of care provided at the transferring hospital.

f. 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. 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 can continue to receive penalties even while they make significant improvements indicates even more the need for CMS to adopt the recommendations in this letter. Given 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 making improvements in reducing unnecessary readmissions.

4. CMS should postpone finalizing any measures for the hospital-acquired conditions (HAC) reduction program, until the methodology and quality measures in the program can be tailored to accurately measure hospitals' improvements on HACs and not disproportionately penalize certain types of hospitals.

CMS should reevaluate the quality measures proposed for implementation in the HAC reduction program because they do not accurately evaluate hospital quality. CMS should also revise its proposed methodology for determining whether a

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¹⁶See, e.g., June 22, 2012, MedPAC Comment Letter on FY 2013 IPPS Proposed Rule at 3.

hospital is penalized because the methodology is skewed against large hospitals and teaching hospitals, which provide essential care to vulnerable populations. The ACA requires the secretary of HHS to adjust payments to hospitals with high rates of HACs. Specifically, for hospitals that rank in the top quartile 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. In the FY 2014 proposed rule, CMS provides guidance on implementing the HAC reduction program, set to begin in FY 2015.

America's Essential Hospitals agrees with CMS' intent in implementing the HAC reduction program, as HACs create serious adverse outcomes for patients and can lead to death or disability. They 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 proposed by CMS, such as the Agency for Healthcare Research and Quality (AHRQ) patient safety indicator (PSI) measures, are unreliable indicators of quality of care, due to the fact that they are claims-based measures and these events occur infrequently. Some of these measures also exist in other programs, so including them in the HAC program will expose hospitals to multiple penalties for the same measures under different programs. CMS has until FY 2015 to implement the HAC reduction program, and as such CMS should delay finalizing any measures for the program until hospitals are able to thoroughly evaluate the appropriateness of the included measures and methodology and the impact these measures will have on hospitals.

CMS proposes two approaches, each consisting of two equally weighted sets (referred to by CMS as "domains") of HAC measures. The individual domain scores are used to calculate a total HAC score, and this score is used to rank hospitals nationally to determine the top quartile. The first domain of HAC measures is different in both approaches, but the second domain is identical in both approaches. To calculate a score for domain 1 under the first approach, CMS proposes to use six AHRQ PSI measures that would be calculated using Medicare fee-for-service claims-based data:

- Pressure ulcer rate (PSI 3)
- Volume of foreign object left in body (PSI 5)
- Iatrogenic pneumothorax rate (PSI 6)
- Postoperative physiologic and metabolic derangement rate (PSI 10)
- Postoperative pulmonary embolism (PE) or deep vein thrombosis (DVT) rate (PSI 12)
- Accidental puncture and laceration rate (PSI 15)

The alternate approach for domain 1 consists of an AHRQ PSI-90 composite measure, which is made up of the following eight component PSIs:

- Pressure ulcer rate (PSI 3)
- Iatrogenic pneumothorax rate (PSI 6)
- Central venous catheter-related bloodstream infection rate (PSI 7)
- Postoperative hip fracture rate (PSI 8)
- Postoperative PE or DVT rate (PSI 12)
- Postoperative sepsis rate (PSI 13)
- Wound dehiscence rate (PSI 14)
- Accidental puncture and laceration rate (PSI 15)

Domain 2, which is identical under both approaches, consists of hospital-acquired infection (HAI) measures collected through the U.S. Centers for Disease Control and Prevention's (CDC's) National Healthcare Safety Network (NHSN). The two CDC HAI measures proposed for inclusion in the FY 2015 program are central line–associated bloodstream infection (CLABSI) and catheter-associated urinary tract infection (CAUTI). The CLABSI measure is proposed for inclusion in the value-based purchasing (VBP) program, and the CAUTI measure is included in the hospital IQR program and proposed for inclusion in the VBP program in FY 2016.

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. CMS' analysis of the effects of the HAC 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, 27 percent of DSH hospitals fall within the top quartile using CMS' first approach for the domain 1 measures, while only 18.9 percent of non-DSH hospitals fall within the top quartile. For teaching hospitals, 56.7 percent fall within the top quartile, compared to 22.8 percent of nonteaching hospitals. For urban hospitals, 29.7 percent fall in the top quartile, compared to 13.2 percent of rural hospitals.

Hospitals that fall into these categories—hospitals such as ours—provide essential care to members of the population who experience challenges receiving care. The patients seeking care at our hospitals tend to be uninsured and from low-income backgrounds, and they frequently do not have access to a post-discharge support structure.

Moreover, many of our hospitals are teaching hospitals and referral 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 accidental puncture and laceration. For example, one member expressed concern that as a tertiary referral center that performs high-risk surgical procedures such as cancer-related surgeries, it has the potential for a higher infection rate than hospitals that do not perform such high-risk procedures. 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 program and exclude measures that are infrequent and more likely to occur in hospitals that fill a safety net role and serve as referral centers and emergency care providers. For these reasons, CMS should reevaluate the measures proposed for implementation 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 program that more accurately reflect hospitals' quality of care.

CMS currently proposes for inclusion in the HAC reduction program 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, 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. 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 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 the high volume 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 HAC scores than other hospitals. Most of the HAC measures occur very infrequently in hospitals across the country, meaning that even a minimal increase in the number of infections can place a hospital in the top quartile for that measure. For these reasons, CMS should propose measures for the HAC reduction program that accurately gauge quality and that 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 program quality measures.

In order to more precisely gauge a hospital's quality on HAC measures, CMS should consider factors such as the patient's location before admission or after discharge and the patient's primary language. The risk-adjustment used for the HAC measures in both domains 1 and 2 are insufficient to account for the many variables outside the control of the hospital that can affect rates of infection. CMS should include risk-

adjustment factors in any measures that it proposes for the HAC reduction program. Location and language are important determinants of a patient's support structure and can contribute to a higher risk of developing an infection. Therefore, these factors should be included in the risk-adjustment methodology, so the measures are more in line with 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)." The unspecified section referred to is section 1886 of the Social Security Act, which includes not only the base operating DRG payment but add-on payments that are critical to our 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 would be unsustainable. 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 be consistent with these programs, and to minimize the disproportionate effect of the program on essential hospitals, the secretary should use her authority to apply the reduction to base operating DRG payments only.

5. CMS should extend the time period hospitals have to initiate the VBP program extraordinary circumstance waiver process.

America's Essential Hospitals supports the addition of an extraordinary circumstance waiver to the VBP program. However, CMS should extend the time period hospitals have to initiate the waiver process from 30 to 90 days after an extraordinary circumstance. An extension would allow hospitals enough time to assess whether or not a waiver is needed to exclude data from the affected time period. Recently, member hospitals in New York mobilized to manage the aftermath of Hurricane Sandy. NuHealth/Nassau Health Care Corporation, in East Meadow, N.Y., took in patients and staff from hospitals and other care facilities on the south shore of Long Island, which suffered a direct hit from Sandy. A federal disaster medical assistance team arrived quickly and stayed for weeks to aid NuHealth staff. Many of these temporary staff members were unfamiliar with NuHealth's electronic health record (EHR) system and had to use paper forms as they treated patients. NuHealth staff then manually entered those data into their system, a time-consuming task that caused a 2-month lag for chart abstractors. NuHealth would not have been able to adequately assess its need for a waiver until the chart abstractors completed their review.

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¹⁷Social Security Act § 1886(p)(1).

Another member, New York City Health and Hospitals Corporation (HHC), sustained heavy damage at many of its facilities. Among the most damaged were Bellevue Hospital Center, Coney Island Hospital, and the Coler campus of Coler-Goldwater Specialty Hospital and Nursing Facility. These facilities lost power, had to relocate patients, and are only now seeing signs of recovery and accepting patients again. In addition, Ida G. Israel Community Health Center, an offsite ambulatory care center of Coney Island Hospital, was irreparably damaged by flooding. HHC is now exploring options for a new site. During the first 30 days following the storm, HHC would not have been able to assess its need for a waiver as it dealt with hospital closures and displaced patients.

Extending the time period from 30 to 90 days for hospitals to initiate the VBP program extraordinary circumstance waiver process would allow hospitals time to assess their need for a waiver. Once a hospital's immediate needs during an extraordinary circumstance are addressed, the hospital may decide it is able to report and would prefer to avoid a gap in data. For these reasons, CMS should extend the time period hospitals have to initiate the VBP program extraordinary circumstance waiver process to 90 days after an extraordinary circumstance to allow sufficient time for hospitals to evaluate their need for such a waiver.

- 6. CMS should only include measures in the VBP program that have been proven to improve patient outcomes.
 - a. CMS should remove measures from the VBP program that are no longer endorsed by the National Quality Forum (NQF) and/or supported by the Measure Application Partnership (MAP) or are considered topped out by CMS.

CMS should finalize its proposal to remove the primary percutaneous coronary intervention (PCI) received within 90 minutes of hospital arrival (AMI-8a) measure, the blood cultures performed in the emergency department prior to initial antibiotic received in hospital (PN-3b) measure, and the discharge instructions (HF-1) measure from the FY 2016 VBP program. CMS proposes to remove the AMI-8a measure, as the agency considers the measure topped out, which means it meets 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. The PN-3b and HF-1 measures are no longer endorsed by NQF or recommended for inclusion by MAP. NQF and MAP routinely reevaluate measures and retire those that are either duplicative or no longer provide meaningful data comparisons that show improvements to patient outcomes. America's Essential Hospitals appreciates any efforts by CMS to reduce the reporting burden on hospitals. By better aligning the quality measures hospitals must track for various reporting programs, 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 2016 program.

b. CMS should also remove the AHRQ PSI composite measure from the FY 2016 VBP program because the measure is unreliable.

The AHRQ PSI composite measure lacks sufficient exclusion criteria, which makes it an unreliable account of the quality of care provided at a hospital. The AHRQ PSI measure is based on administrative claims data, which do not contain a sufficient amount of clinical information. Therefore, many patients could be included in the numerator who would be appropriately excluded based on a review of their more-detailed clinical record. Thus, the resulting data provide an inaccurate account of patient safety levels at the hospital. However, the PSI composite measure is unreliable and should be refined before inclusion in the VBP or any other quality improvement program. For these reasons, CMS should eliminate the AHRQ PSI composite measure from the VBP program.

c. CMS should remove the influenza immunization (IMM-2, NQF #1659) measure from the FY 2016 VBP program.

CMS should remove the IMM-2 measure from the FY 2016 VBP program because hospital inpatient departments are not the appropriate site for collecting data for this measure. Many patients who receive care from other providers before being admitted to the hospital are immunized prior to the hospital admission. Hospitals cannot administer the immunization again or capture that the patient has received the immunization. America's Essential Hospitals recognizes the importance of influenza immunizations and urges CMS to review the best point of patient contact for administering this immunization and collecting corresponding data. For these reasons, CMS should remove the IMM-2 measure from the FY 2016 VBP program.

d. CMS should ensure the surgical site infection (SSI, NQF #0753) measure is properly risk-adjusted before including it in the FY 2016 VBP program.

CMS proposes to adopt for the VBP program the SSI measure currently specified under the IQR program, which is restricted to colon procedures, including incision, resection, or anastomosis of the large intestine; large-to-small and small-to-large bowel anastomosis; and abdominal hysterectomy procedures, including those done by laparoscope. However, failure to fully risk-adjust this measure by both demographic and socioeconomic factors can potentially penalize essential hospitals for social and community factors unrelated to the quality of care they provide. America's Essential Hospitals' members have struggled with this measure in the IQR program due to the patient populations they serve. Specifically, our members provide care to a high number of obese patients, who have been shown to have an increased rate of SSI compared with non-obese patients undergoing colorectal surgery. For this reason, CMS should ensure the SSI measure is properly risk-adjusted before including it in the FY 2016 VBP program.

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¹⁸Elizabeth C. Wick, K. Hirose, et al. "Surgical Site Infections and Cost in Obese Patients Undergoing Colorectal Surgery," *Archives of Surgery* 146, no. 9 (2011):1068-1072.

e. CMS should suspend inclusion of the CLABSI measure in the FY 2016 VBP program.

CMS should wait to include the NHSN-based CLABSI measure in the VBP program or any other quality improvement program until the CDC's new, reliability-adjusted measure is endorsed by NQF. America's Essential Hospitals supports the tracking and measuring of the CLABSI measure, which assesses the rate of laboratory-confirmed cases of bloodstream infection or clinical sepsis among patients in the ICU. The measure is reported through the CDC's NHSN. CMS noted that the 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 FY 2015 CLABSI measure for the FY 2016 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, 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 NQF and hospitals are given time to gain experience reporting the revised measure.

f. 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 until hospitals gain more experience reporting them. These measures are high-priority HAI measures, but have only been recently endorsed by NQF. Hospitals need time to gain experience reporting them so the information reported reflects the existence or absence of these infections, and not something else due to potential data anomalies. America's Essential Hospitals supports quality improvements to decrease the incidence of these infections. However, it is important to ensure data are accurate so hospitals are not erroneously penalized. Therefore, CMS should delay inclusion of these infection ratio measures in the VBP program to allow hospitals to gain experience reporting them.

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

CMS proposes to align quality improvement efforts with the priorities developed under the program. CMS proposes to combine the priorities of care coordination and person and caregiver–centered experience of care into one domain. CMS also proposes two possible structures for the domains and weights in the program for FY 2017. The first proposed structure would include the following domains and weights: safety with a weight of 15 percent, clinical care (with process and outcome measures) at 35 percent, efficiency and cost reduction at 25 percent, and care coordination at 25 percent. CMS also proposes an alternative structure, which would implement the proposed FY 2016 VBP program domain and weights structure. CMS proposes the following domains and weights for that structure: clinical process of care at 10 percent, patient experience of care at 25 percent, outcome at 40 percent and efficiency at 25 percent. More specific comments on the proposal are included below.

a. CMS should raise the proposed weight for the clinical process of care domain for FYs 2016 and 2017 to focus on improved patient outcomes.

CMS should raise the weight (e.g., to 40 percent) for the proposed FY 2017 weighting for the clinical process of care domain. Raising the weights would increase the emphasis on clinical process of care measures, which should translate into improved patient outcomes. In addition, the clinical process of care domain has more measures than other domains and should have a significantly higher weight than other domains. For these reasons, CMS should raise the weight of the clinical process of care domain for FYs 2016 and 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 both FYs 2016 and 2017 measure sets, 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. Rather, the domains should be more equally balanced to ensure hospitals are focused both on improving patient outcomes and increasing efficiency. For these reasons, CMS should lower the weight of the efficiency domain for FYs 2016 and 2017.

8. CMS should continue to refine the hospital IQR program by removing measures that have been topped out, changed, or are not endorsed by NQF and/or supported by MAP.

CMS should finalize its proposal to remove a number of measures from the FY 2016 IQR program. The proposed removals appropriately eliminate measures that are topped out, have significantly changed, or are no longer endorsed by NQF and/or supported by MAP. The following measures would be removed from the program:

- Blood culture performed in the emergency room prior to first antibiotic received in the hospital (PN-3b)
- Discharge instructions (HF-1)

- Immunization for pneumonia (IMM-1)
- Systematic clinical database registry for stroke care
- Aspirin prescribed at discharge (AMI-2)
- Statin prescribed at discharge (AMI-10)
- Angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) for left ventricular systolic dysfunction (LVSD) (HF-3)
- Surgery patients with perioperative temperature management (SCIP-Inf-10)

America's Essential Hospitals appreciates any efforts by CMS to reduce the reporting burden on hospitals and remove measures that no longer add value to the IQR program. For these reasons, CMS should finalize this proposal and remove these measures from the FY 2016 IQR program.

a. CMS should not include any measures in the IQR program that are not endorsed by NQF and/or supported by MAP.

CMS should not include the hospital 30-day, all-cause risk-standardized rate of readmission following acute ischemic stroke (stroke readmission) measure, the allcause risk-standardized rate of mortality following an admission for acute ischemic stroke (stroke mortality) measure, and the hospital risk-standardized payment associated with a 30-day episode-of-care for AMI measure in the FY 2016 IQR program because the measures have not been endorsed by NQF and/or supported by MAP. CMS proposes to include these measures for FY 2016 using its exception authority, as these measures have not been endorsed by NQF or supported by MAP. America's Essential Hospitals supports the creation and implementation of measures that lead to quality improvements. However, CMS must certify that the measures are properly constructed and do not lead to unintended consequences prior to inclusion in the IQR program. CMS should also ensure new measures are included in the IQR program for at least 2 years before adding those measures to other quality improvement programs. Endorsements by organizations such as NQF and MAP lend validity and legitimacy to the measures. For these reasons, CMS should not include the stroke readmission measure, stroke mortality measure, or the AMI payment measure in the FY 2016 IQR program.

b. CMS should align the IQR program with NQF endorsement maintenance decisions.

America's Essential Hospitals supports aligning IQR program measures with NQF endorsement maintenance decisions and urges CMS to finalize its proposal to incorporate the planned readmission algorithm into the readmission measures. For FYs 2015 and 2016, CMS proposes to refine current measures in the IQR program. America's Essential Hospitals supports CMS' proposal to incorporate the planned readmission algorithm into the 30-day readmission measures for AMI, HF, PN, and THA/TKA. These proposals match NQF endorsement maintenance decisions beginning in 2013. NQF endorsement maintenance decisions are the result of careful review of

previously endorsed measures and ensure hospitals are being held to the most recent, thoroughly vetted measures. For these reasons, CMS should align the IQR program measures with NQF endorsement maintenance decisions and finalize its proposal to incorporate the planned readmission algorithm into the readmission measures.

c. CMS should extend the implementation time frame for expanding CLABSI and CAUTI measures to select non-ICU locations and refining the surgical care improvement project infection 4, cardiac surgery patients with controlled 6 am postoperative blood glucose (SCIP Inf 4) measure.

CMS proposes expanding CLABSI and CAUTI measures to select non-ICU locations in hospitals beginning with infections occurring on or after Jan. 1, 2014. CMS also proposes refining the SCIP Inf 4 measure to match NQF refinements beginning with Jan. 1, 2014 discharges. Although these changes are consistent with NQF endorsements, CMS should delay the time frame. The proposed changes would leave hospitals with less than 1 year to make the appropriate adjustments necessary for collecting data and reporting these measures. This short time frame could compromise the reliability and validity of the measures and may result in financial penalties that do not accurately reflect hospitals' comparative performance. America's Essential Hospitals supports the proposed changes, but urges CMS to allow hospitals adequate time to make the necessary adjustments to accurately report CLABSI and CAUTI measures in select non-ICU locations and refine the SCIP Inf 4 measure.

d. CMS should perform thorough public testing and review of measure data before making them publically available.

CMS proposes to make publically available hospital data for the PSI indicators that are part of the PSI-90 composite, in addition to the composite results that are already publicly available, and solicits comment on other quality measures that would be relevant to the public. America's Essential Hospitals is concerned the general public would have difficulty understanding the nuances of the PSI composite and the individual PSI indicators. Depending on how the PSI composite and indicators are displayed (e.g., reported as a rate), the public could be misled on the quality and safety of a hospital. CMS should ensure all information made available to the public is executed with a comprehensive and complete approach so data are presented in the right context. America's Essential Hospitals does not support using star ratings of aggregate measures to display information on Hospital Compare. Instead, CMS should categorize and group similar hospitals on Hospital Compare so comparisons are relative and clear to the public. In general, thorough public testing and vetting must be undertaken before CMS makes any data available to the public.

9. CMS should ensure electronic reporting is a viable option for all hospitals and work with an independent evaluator to understand any variance created through electronic reporting.

CMS should work with EHR vendors to make the Medicare EHR Incentive Program Electronic Reporting Pilot a viable option for all hospitals. CMS proposes to allow hospitals to voluntarily electronically report 16 measures across four measure sets for the FY 2016 IQR program. While America's Essential Hospitals supports this proposal, we remain concerned about participation levels in the Medicare EHR Incentive Program Electronic Reporting Pilot for eligible hospitals and critical access hospitals. Not a single member of America's Essential Hospitals is participating in the 2012 pilot program because members' EHR vendors have not yet devoted the resources to ensure their products can support the type of information exchange needed to participate. To secure sufficient vendor participation, CMS must be more flexible with the pilot's patient-level data transfer standards—e.g., by adopting data transmission standards that EHR vendors are already using. Without vendor support, most hospitals find it impossible to participate in the pilot. 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 and are using different EHR vendor products to electrically report clinical quality measures. If the challenges faced by hospitals in the EHR pilot program have yet to be appropriately addressed, hospitals will continue to face the same challenges as they voluntarily electronically report the proposed measure sets for the IQR program. Therefore, CMS should continue to work with EHR vendors to make electronic reporting a viable option for all hospitals.

CMS should also work with an independent evaluator to understand any variance created through electronic reporting. Before CMS requires hospitals to submit quality measures electronically, even on a voluntary basis, a head-to-head comparison between electronically reported and manually abstracted data is necessary to test the reliability of electronically reported data. Therefore, CMS should work with an independent evaluator to understand any variance created with electronic reporting.

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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,

Bruce Siegel, MD, MPH

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President and Chief Executive Officer