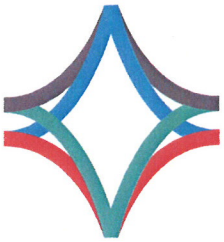

September 2, 2014

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–1613–P: Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Physician-Owned Hospitals: Data Sources for Expansion Exception; Physician Certification of Inpatient Hospital Services; Medicare Advantage Organizations and Part D Sponsors: Appeals Process for Overpayments Associated With Submitted Data

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. To this end, we ask CMS to consider the unique challenges inherent in caring for our nation's most vulnerable patient populations when finalizing this rule. Filling a safety net role in their communities, essential hospitals serve patient populations with unique needs, and thus are at risk of being disproportionately negatively impacted by certain regulations.

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 nearly 250 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 all hospitals nationwide.[1]

As ECPs, our members also offer specialized outpatient and emergency services, such as trauma and burn care, which are not available elsewhere in their communities. In the 10 largest U.S. cities, our members operate 32 percent of all level I trauma centers and 38 percent of all burn-care beds.[2] Our members provide access to high-quality health care for all patients, predominantly serving patients covered by public programs and the uninsured. In fact, 18 percent of the outpatient services provided by our members are to Medicare beneficiaries, another 27 percent are to Medicaid recipients, and 29 percent are to uninsured patients.[3]

Members of America's Essential Hospitals play a vital role in providing ambulatory care to their communities. The average member operates a network of 20 or more ambulatory care sites. And in 2012, the average member saw more than four times as many non-emergency outpatient visits as other acute care hospitals nationwide. Our members also offer more comprehensive ambulatory care than many other providers and create medical homes for community residents through networks of provider-based ambulatory health clinics. For example, their hospital-based clinics include onsite features such as radiology, laboratory, and pharmacy services, which are not typically offered at freestanding physician offices. And they deliver ambulatory care services to schools and housing developments through mobile units, many of which offer onsite behavioral health support services, interpreters, and patient advocates who can access support programs for patients with complex medical and social needs.

Members of America's Essential Hospitals find increasingly innovative and efficient strategies for providing high-quality, complex care to their patients, all while facing high costs with limited resources. 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 cuts in the Affordable Care Act and other hospital cuts Congress has targeted to offset federal spending.

To ensure essential hospitals 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.

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[1]Reid K, Roberson B, Laycox S, Linson M. Essential Hospitals Vital Data: Results of America's Essential Hospitals Annual Characteristics Survey, FY 2012. America's Essential Hospitals. July 2014. http://2c4xez132caw2w3cpr1il98fssf.wpengine.netdna-cdn.com/wp-content/uploads/2014/08/VitalData-FullReport-20140804.pdf. Accessed August 2014.

[2]Ibid.

[3]Ibid.

1. CMS should ensure its comprehensive ambulatory payment classification (C-APC) proposal does not disproportionately impact hospitals treating more diverse and clinically complex patients.

CMS should ensure its C-APC proposal includes a complexity adjustment that accounts for patient complexity, so the policy does not adversely affect essential hospitals, which treat sicker patients and perform more complex procedures compared to the average hospital. **Moreover, until an appropriate adjustment is developed and implemented, CMS should gradually phase in its proposal for a smaller set of C-APCs.** CMS intends to implement its calendar year (CY) 2014 policy to create C-APCs that would package payment for device-dependent procedures with other services that appear on the claim and were provided in association with the primary device-dependent procedure. Instead of paying hospitals the regular APC amount just for the device-dependent procedure and paying separately for related services and supplies, CMS will package all adjunctive services provided in association with the primary procedure into a single C-APC payment. Adjunctive services include diagnostic procedures, laboratory tests, imaging services, and blood and blood products. Payments that are typically not made under the Outpatient Prospective Payment System (OPPS) but under a separate fee schedule, including payment for durable medical equipment, would also be paid under the OPPS as part of C-APC payment.

To calculate the relative payment weight for the C-APC, CMS uses the geometric mean of the estimated costs of claims for device-dependent procedures and all adjunctive services. Thus, a hospital would receive a single global payment, regardless of the cost of the device-dependent procedure at the particular hospital, the intensity of the services provided, how sick and medically complicated the patient receiving treatment is, or the number and cost of adjunctive services provided in conjunction with the primary procedure.

Such a policy could have an adverse impact on essential hospitals. Certain types of tests or diagnostic procedures may be performed more often at essential hospitals, most of which are academic medical centers providing high-acuity care and treating sicker patients. The C-APC policy could put essential hospitals at a disadvantage due to the greater number of resources needed to provide high-acuity care to clinically complex patients.

CMS proposes a complexity adjustment under the C-APC policy that only accounts for identified instances of high-cost combinations of device-dependent procedures. It does not account for patient characteristics. For example, to account for complex cases in which more than one device-dependent procedure appears on a claim, CMS will apply a complexity adjustment and pay the hospital the next-highest C-APC amount in the clinical family. CMS has identified 52 different higher-cost procedure combinations to which it will apply a complexity adjustment. While this type of complexity adjustment will account for certain higher-cost cases, it still does not take into account patient characteristics, such as comorbidities and socioeconomic factors. The adjustment as

outlined by CMS also would not account for cases in which only one device-dependent procedure is performed, but due to the patient's particular characteristics and comorbidities, more resources are needed to treat the patient.

Due to the higher complexity of the procedures performed and the patients treated at essential hospitals, CMS should account for clinical complexity and patient characteristics when paying a hospital under the C-APC. Members of America's Essential Hospitals strive to provide high-quality care efficiently to their patients. Given their lower margins compared to hospitals nationally, essential hospitals must find innovative ways to provide care. Essential hospitals have an average payer mix of 56 percent Medicaid or uninsured patients. In addition, 43 percent of essential hospitals have a negative operating margin, compared to 26 percent nationally. And these hospitals are still able to use their resources efficiently. Essential hospitals deliver more cost-efficient care than other hospitals nationwide, scoring slightly below the national median for the Medicare spending per beneficiary measure.[4] But their diverse mix of patients, in terms of clinical complexity and sociodemographic factors, complicates care and requires an intensity of resources.

Essential hospitals also provide a range of care including trauma and burn care. Accordingly, essential hospitals often incur higher costs when providing care compared to hospitals with less complex patients and less resource-intensive services. **Therefore, CMS should account for such cases by adjusting for patient complexity in its complexity adjustment. Until CMS can implement an appropriate adjustment, CMS should gradually phase in the proposal for a smaller subset of C-APCs instead of implementing the entire proposal for all 28 C-APCs in CY 2015.**

2. CMS should not adopt a claims-based modifier for off-campus provider-based departments and instead should work closely with the hospital industry to develop a data collection methodology that accurately captures the type of care provided in this setting.

CMS should not finalize its proposal to use a claims-based modifier for off-campus provider-based departments because this approach would not capture the spectrum of services patients in these departments need and receive and would impose an administrative cost and burden on hospitals' billing departments. Instead, CMS should convene a workgroup that includes the hospital industry to collaborate on how best to collect the data needed to accurately capture the care provided in off-campus provider-based departments. In the CY 2014 proposed rule, CMS noted a desire to better understand the growing trend of hospitals acquiring physician offices and then treating those offices as off-campus, provider-based outpatient departments. In response, CMS proposes to collect data to analyze the frequency and type of, as well as payment for, services furnished in these departments. While CMS did not finalize a data collection method last year, in this year's rule CMS is proposing to require hospitals to

[4]Ibid.

report a Healthcare Common Procedure Coding System (HCPCS) modifier with every code for outpatient hospital and physician services provided in off-campus provider-based departments. This modifier would be reported on hospitals' UB-04 form (CMS form 1450) and on physicians' CMS-1500 claim form.

America's Essential Hospitals commends CMS for seeking out more information to fully understand the differences between care provided in these settings and care provided in freestanding physician offices. However, to make a fair assessment, CMS must fully understand the role these off-campus provider-based departments play in ensuring access to quality care for beneficiaries, and the proposed modifier would not capture this information.

Over time, members of America's Essential Hospitals have significantly expanded their outpatient presence in their communities through on-campus hospital clinics, off-campus community clinics, and mobile units. Though this type of expansion has required a substantial investment of hospital resources, it has allowed member hospitals to offer critical outpatient services to vulnerable patients, including those dually eligible for Medicare and Medicaid.

As major providers of outpatient specialty care, a vital service for low-income communities who often do not have access to private physician offices, essential hospitals often include in their off-campus departments pharmacy, radiology, mammography, ancillary support, opticians, dermatology clinics, and other services low-income beneficiaries rely on. In this way, our members help ensure their communities have access to quality specialty care through these provider-based off-campus departments. In particular, the integration between providers that result from hospital-operated off-campus provider-based departments is critical to the success of achieving affordable, high-quality care for all. This is especially true for integration that occurs in essential hospital systems that care for the most vulnerable among us. Such detail is not captured in the proposed modifier to collect data.

The data-collection methods CMS is considering could not quantify all services needed by patients that receive care in these outpatient departments or the savings resulting from keeping these patients out of the emergency department (ED), decreasing ED wait times and reducing costly hospital admissions. To truly understand the difference in patient need and the impact of these important benefits, CMS should work with the hospital industry to develop a methodology that would foster a full analysis of the vital care patients receive in provider-based off-campus outpatient departments.

America's Essential Hospitals is also concerned that CMS' proposed approach would impose an excessive burden on hospital administrators responsible for billing practices. Hospital outpatient claims can encompass different services spanning multiple days and different sites. Services on hospital claims are not always differentiated by whether they are provided on campus or off campus. Therefore, it would be difficult for billing personnel to adapt their systems to distinguish between services provided in on-campus

and off-campus hospital outpatient departments. Requiring hospitals to report a location-based modifier would take a significant investment of time and resources. Hospital billing personnel would have to ensure the modifier is added to each line of a claim representing a service provided in an off-campus provider-based department. They would do this either by building the modifier into their systems or adding the modifier to each service on an ongoing basis. Any time that a hospital adds a new service to its system it would have to repeat the process to ensure the modifier is in place. Additionally, the fact that CMS is requiring the modifier to be on each line of the claim representing an additional burden, not only for coding efforts but also for continuous review and compliance efforts.

Furthermore, while physicians report place of service codes for hospital outpatient services, they do not distinguish between on-campus and off-campus locations. CMS' proposal would mean that physician business offices will have to know whether a hospital department is off campus or on campus, again increasing the compliance risk. Due to the complexity of this change, hospitals may not be prepared for this new requirement in time for CY 2015. For these reasons, **prior to any data collection efforts, CMS should convene a workgroup that includes the hospital industry to collaborate on how best to collect the data needed to accurately capture the care provided in off-campus provider-based departments in a manner that is not unduly burdensome.**

3. CMS should not collapse codes for ED visits because doing so would disproportionately impact hospitals providing complex care.

America's Essential Hospitals supports CMS' decision not to adopt any changes in coding and payment for type A and type B ED visits until the agency has conducted a thorough evaluation of its proposal and meaningfully evaluates the impact on hospitals that provide complex care, such as essential hospitals with trauma centers. Prior to CY 2014, there were 10 levels of clinic visits (5 for new patients and 5 for existing patients), 5 levels of type A ED visits (EDs that are open 24 hours a day, 7 days a week), and 5 levels of type B ED visits (EDs that are open fewer than 24 hours a day, 7 days a week). In the CY 2014 OPPS proposed rule, CMS sought to collapse the existing levels of clinic and ED visits into a single level for each type of visit by creating three new level II HCPCS codes. One code (GXXXC) would be used for hospital outpatient clinic visits for both existing and new patients; one code (GXXXA) would be used for type A ED visits; and one code (GXXXB) would be used for type B ED visits. CMS further proposed to calculate payment rates for the three new codes based on the average cost of all levels currently in use for each visit type. In the CY 2014 OPPS final rule, CMS finalized its proposal to create a new level II HCPCS code for hospital outpatient clinic visits, but did not finalize its proposal to collapse the codes into a single level for types A and B ED visits.

Members of America's Essential Hospitals treated more than 7.2 million patients in their EDs in 2012. Moreover, our member hospitals provide roughly one-third of critical and specialty services in the 10 largest cities in the United States, which are home to more

than 25 million people. These complex services include, but are not limited to, level I trauma centers, burn care beds, and psychiatric care beds.[5] Communities across the country rely on these vital services our members provide. Changes to coding for ED visits, such as those previously proposed by CMS, would disproportionately impact essential hospitals that provide this needed care and thus have extremely active EDs where the most critically injured and sick patients receive care. **Therefore, we support CMS' decision to not collapse codes for ED visits until it conducts the necessary evaluations and ensures any changes are structured in a way to mitigate the negative impact on essential hospitals that provide complex, critical care.**

4. CMS should continue to refine the Outpatient Quality Reporting (OQR) Program measure set so it contains only reliable and valid measures that provide an accurate representation of hospital quality of care in the outpatient setting.

CMS should continue to tailor the OQR Program measure set so it includes measures that are useful to hospitals as they work to improve the quality of their care and beneficial to the public as an accurate reflection of 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 OQR Program.

CMS proposes to add one measure to the OQR Program and remove three measures for the CY 2017 payment determination. America's Essential Hospitals supports removing measures that no longer accurately capture distinctions in quality of care. Removing these measures reduces the administrative burden on hospitals and ensures the OQR measure set is kept up to date. However, measures that are identified as topped out should be kept in place for a period of at least two years to continue to encourage the use of clinical processes that enhance health outcomes. Any new measures that are added should be reliable, valid, and useful in improving the quality of hospital care and the transparency of public reporting.

a. CMS should not add the OP-32 colonoscopy measure to the OQR Program because it is not endorsed by the National Quality Forum (NQF) and is not appropriately risk adjusted.

CMS proposes to add the claims-based OP-32 measure to the OQR Program beginning with the CY 2017 payment determination. This measure captures the facility seven-day risk-standardized hospital visit rate after outpatient colonoscopies. It assesses hospitals for the rate of unplanned hospital visits that occur within seven days of the outpatient colonoscopy procedure. Hospital visits include observation stays, inpatient admissions,

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[5]Reid K, Roberson B, Laycox S, Linson M. Essential Hospitals Vital Data: Results of America's Essential Hospitals Annual Characteristics Survey, FY 2012. America's Essential Hospitals. July 2014. http://2c4xez132caw2w3cpr1il98fssf.wpengine.netdna-cdn.com/wp-content/uploads/2014/08/VitalData-FullReport-20140804.pdf. Accessed August 2014.

and ED visits. Because this is an all-cause measure, all unplanned hospital visits, regardless of the underlying reasons for the visit, would count against the hospital.

CMS should not include this measure in the OQR Program because NQF has not yet endorsed it and the Measure Applications Partnership (MAP) conditionally supported the measure, noting the need for NQF endorsement. The measures in the OQR Program should be endorsed by NQF and recommended by MAP as reliable, leading to improved clinical outcomes, suitable for public reporting, and ready to be implemented. NQF endorsement is imperative to ensure measure validity and reliability, as the endorsement process requires measures to be fully vetted and approved through a consensus-building approach that involves the public and interested stakeholders.

In addition to the lack of NQF endorsement, the measure methodology lacks adjustment for important factors, including socioeconomic factors. For outcome performance measures such as the OP-32 colonoscopy measure, CMS should incorporate risk adjustment for socioeconomic factors in its methodology so the results are accurate and reflect differences in the patients being treated across hospitals. Without proper risk adjustment, a hospital that serves a disproportionate share of lower-income patients with confounding socioeconomic factors may have more unplanned visits following outpatient procedures for reasons outside of the hospital's control. Results on this type of measure can be skewed by factors such as race, homelessness, cultural and linguistic barriers, and low literacy. Patients who do not have a reliable support structure upon discharge are more likely to be readmitted to a hospital or other institutional setting. These readmissions are caused by factors beyond the control of the hospital and therefore do not reflect the quality of care being provided. Risk adjusting measures for these factors will ensure the resulting information is more useful to the public in assessing the quality of care provided at hospitals.[6] For these reasons, **CMS should not add the OP-32 measure to the OQR Program.**

b. CMS should use consistent criteria across public reporting programs to determine which measures are topped out but should not prematurely remove measures that encourage clinical processes leading to better health outcomes.

To help align its criteria for determining which measures should be removed across public reporting programs, CMS should finalize its proposal to identify topped out measures with a modification to ensure measures are not prematurely removed. CMS proposes to refine its criteria for determining which measures are topped out and should be removed from the OQR Program. Topped out measures are those for which performance is high and doesn't vary across hospitals, so meaningful distinctions and improvements in performance are no longer feasible. Under the proposal, a measure in the OQR Program would be deemed topped out if it meets two criteria:

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

- statistically indistinguishable performance at the 75th and 90th percentiles
- a truncated coefficient of variation less than or equal to 0.10.

CMS adopted these criteria for the Inpatient Quality Reporting Program in the FY 2015 Inpatient Prospective Payment System final rule. CMS also uses nearly identical criteria for the Value-Based Purchasing Program. 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. In the same way, by finalizing identical criteria for determining topped out status across the various quality reporting programs, CMS can add to these efforts and ensure consistency and alignment across programs.

In addition, once CMS settles on a new set of criteria, the agency should ensure all measures meeting the new criteria have done so for at least two years before removing them from a reporting program. This way, hospitals can continue to institute clinically effective processes to improve patient care for the wide array of measures included in the various programs. **For the OQR Program, CMS should finalize its proposal with the modification that measures be deemed topped out for at least two years before being removed.**

For the following three measures identified by CMS as being topped out, the agency should evaluate these measures using criteria that incorporate the recommended modification:

- OP-4: Aspirin at Arrival (NQF # 0286)
- OP-6: Timing of Antibiotic Prophylaxis
- OP-7: Prophylactic Antibiotic Selection for Surgical Patients (NQF # 0528)

If these measures meet the criteria with the recommended modification, only then should they be removed from the OQR Program.

c. CMS should remove the OP-31 measure from the OQR Program, as it is not appropriate for measuring quality at the facility level.

CMS should remove the OP-31 measure from the program because it places an unnecessary burden on hospitals that does not result in corresponding improvements in care. CMS proposes to exclude the OP-31 measure (Cataracts - Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery [NQF #1536]) from the CY 2016 payment determination and to change the measure from required to voluntary reporting beginning with CY 2017. Data voluntarily submitted by hospitals on this measure would be publicly reported but hospitals would not face a payment reduction for choosing not to submit data on this measure. Since the adoption of this measure in the CY 2014 OPPS final rule, CMS has delayed data collection twice due to issues with collecting data for this measure in hospital outpatient departments.

CMS notes in the proposed rule that contrary to its previous statements, the measure has not been field tested for the hospital outpatient department setting. America's Essential Hospitals appreciates the agency's decision to exclude this measure from the program. **However, because this measure is not appropriate for the hospital outpatient setting, it provides little value as a voluntary measure and should be removed completely.**

5. CMS should finalize its proposed statutory default payment for separately payable drugs and biologicals.

For CY 2015, CMS proposes to continue its CY 2014 policy and set the reimbursement rate of the statutory default of average sales price (ASP) plus 6 percent for separately payable drugs and biologicals that do not have pass-through status (i.e., specified covered outpatient drugs [SCODs]). Since CY 2006, CMS has used an ASP + 4 to ASP + 6 percentage range for separately payable drugs and biologicals administered in the hospital outpatient department to account for acquisition and pharmacy overhead and related expenses.

America's Essential Hospitals is pleased CMS continues to propose this statutory default, which will create more consistency with the reimbursement rates set for other types of drugs, and urges CMS to continue to refine this formula to more adequately account for overhead costs. In summary, **CMS should finalize its ASP + 6 percent default payment rate for drugs and biologicals as proposed.**

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

Sincerely,

Bruce Siegel, MD, MPH
President and CEO