AMERICA'S ESSENTIAL HOSPITALS

September 6, 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-1601-P: Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment System (OPPS), Ambulatory Surgical Center Payment System, and Quality Reporting Programs; Hospital Value-Based Purchasing Program; Organ Procurement Organizations; Quality Improvement Organizations; Electronic Health Records (EHR) Incentive Program; Provider Reimbursement Determinations and Appeals

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. 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, so that essential hospitals—those that fill a safety net role in their community—are not disproportionately impacted due to the unique needs of the patient populations they serve.

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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. As essential community providers, our members also offer specialized outpatient and emergency services, such as trauma and burn care, which are not available elsewhere in their community. In the 10 largest U.S. cities, our members operate 37 percent of all level I trauma centers and 57 percent of all burn-care beds.[1] Our members provide access to high-quality health care for all patients regardless of their ability to pay, predominantly serving patients covered by public programs and the uninsured—17 percent of the outpatient services provided by our members are to Medicare beneficiaries, another 28 percent are to Medicaid recipients, and 30 percent are to uninsured patients.[2]

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 2010 the average member saw almost five times as many non-emergency outpatient visits as other acute care hospitals in the country, and three times as many as those seen at other acute care hospitals in their market. In sum, members of America's Essential Hospitals logged more than 46 million non-emergency outpatient visits in 2010, almost a 100 percent increase since 2000.

Beyond volume, our members offer more comprehensive ambulatory care than many other providers. For example, their hospital-based clinics include onsite features such as thorough radiology, laboratory, and pharmacy services, which are not typically offered at freestanding physician offices. Our members create medical homes for community residents through networks of provider-based ambulatory health

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[1]Obaid 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

[2]Ibid.

clinics. 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 looming 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.

1. CMS should work closely with the hospital industry to develop a data collection methodology that accurately captures the type of care provided in off-campus provider-based outpatient departments.

In particular, 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 calendar year (CY) 2014 proposed rule, CMS notes 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. CMS is concerned about the proliferation of these acquisitions and the increased payments these outpatient departments receive for their services. The Medicare Payment Advisory Commission and media have also recently brought attention to this issue. In response, CMS proposes to collect data to analyze the frequency and type of, as well as payment for, services furnished in these departments.

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 of these issues, CMS must fully understand the role these off-campus provider-based departments play in ensuring access to quality care for beneficiaries. In particular, the integration between providers that result from hospitals operating 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.

Over time, members of America's Essential Hospitals have significantly expanded their outpatient presence in their community 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, 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 care through these provider-based off-campus departments.

To collect data for an in-depth analysis of these departments, CMS considers using either a claims-based approach or asking hospitals to break out these departments' costs on the Medicare cost report. America's Essential Hospitals is concerned that neither of these methods would accurately capture the spectrum of services patients in these departments need and receive. For example, patients receiving care in these departments can access the resources of an acute care facility. The vulnerable populations these outpatient departments serve often delay or cannot access much needed specialty care. Attending physicians in these outpatient departments can quickly utilize ancillary services (i.e., radiology and diagnostic tests) to diagnose and treat these patients in one setting. Physicians can also avoid costly hospital and emergency department (ED) admissions by treating those patients who present with more serious conditions as outpatients.

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 patients out of the 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. **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.**

2. CMS should not finalize its proposal to adopt three new codes to describe all levels of clinic and ED visit types.

CMS should not finalize its proposal to adopt three new codes to describe all levels of hospital outpatient clinic and ED visit types until the agency has provided additional information and made the necessary corrections to its methodology so hospitals can meaningfully evaluate the impact of the proposed changes. CMS proposes to modify long-standing policies regarding payment for hospital outpatient clinic and ED visits. Currently, the OPPS includes 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).

Effective Jan. 1, 2014, CMS proposes 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 healthcare common procedure coding system (HCPCS) codes. One code (GXXXC) will be used for hospital outpatient clinic visits for both existing and new patients; one code (GXXXA) will be used for type A ED visits; and one code (GXXXB) will be used for type B ED visits. CMS further proposes to calculate payment rates for the three new codes based on the average cost of all levels currently in use for each visit type.

America's Essential Hospitals worked with The Moran Company, a health care research and consulting firm, to analyze this proposal. Through this work, we found that we are unable to substantiate CMS' published impact of this proposed policy change. Additional findings

include inconsistent treatment of procedures that are paid for separately as opposed to being packaged with other procedures, and lack of clarity as to whether the new code for clinic visits will be included on the bypass list when some, but not all, of the existing codes are listed on the bypass list. Being on the bypass list may affect, among other things, payment determinations for other procedures. **Until CMS can provide additional information and make the necessary corrections to its methodology so hospitals can meaningfully assess the impact of and comment on the proposed changes, the agency should not finalize this proposal.**

3. CMS should not add additional measures to the hospital outpatient quality reporting (OQR) program and should ensure the measures currently in the program are consistent with National Quality Forum (NQF) endorsements and Measure Applications Partnership (MAP) recommendations.

CMS should not add new measures to the OQR program and should ensure all measures in the program are NQF-endorsed and recommended by the MAP. Under the OQR program, CMS requires hospitals receiving payment reimbursements through the Medicare OPPS to collect and report quality data from the outpatient care setting. Hospitals that fail to meet the data collection and reporting requirements established by the program face financial penalties of up to a 2 percentage point reduction in their annual market basket. Data that hospitals report to CMS are posted publicly on the Hospital Compare website.

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. 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. By better aligning the quality measures hospitals must track for various reporting programs, CMS will not only ensure the measures' reliability but also enable hospitals to use their limited resources for quality improvement as opposed to reporting activities. Adding excessive measures will adversely affect members of America's Essential Hospitals and their ability to serve the nation's most vulnerable populations. For these reasons, **CMS should not add additional measures to the OQR program and should ensure**

current measures are consistent with NQF and MAP recommendations.

a. CMS should clarify the year in which the OP-19 and OP-24 measures will be removed from the OQR program.

CMS should clarify whether it proposes to remove the OP-19 and OP-24 measures beginning with the CY 2015 or CY 2016 payment determination. CMS proposes to remove two measures from the OQR program:

- OP-19: transition record with specified elements received by discharged ED patients
- OP-24: cardiac rehabilitation measure – patient referral from an outpatient setting

CMS notes that it will remove these measures beginning with the CY 2016 payment determination. However, in other parts of the proposed rule, CMS states that it will remove these measures beginning with the CY 2015 payment determination.[3] **Given the inconsistency of the information in the proposed rule, CMS must confirm the correct year in which these two measures will be removed.**

b. CMS should remove existing measures from the OQR program that are not endorsed by the NQF.

CMS should remove measures from the OQR program that are not NQF-endorsed. Specifically, CMS should remove the OP-9, OP-10, OP-14, OP-15, OP-20, OP-22, and OP-25 measures from the OQR program. America's Essential Hospitals expressed reservations regarding the inclusion of these measures and called for their removal in comments on the CY 2013 OPPS proposed rule because they were not NQF-endorsed or MAP-supported. Other national hospital associations echoed these concerns, also calling for the removal of these seven measures in their comments.[4] MAP supported the removal of

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[3]OPPS Proposed Rule CY 2014, 78 *Federal Register* 43653, July 19, 2013 ("For the CY 2015 payment determination and subsequent years, we are proposing to remove OP-19 as discussed in section XIII.C.2.a of this proposed rule.").

[4]American Hospital Association, Comments to CMS on CY 2013 OPPS Proposed Rule, August 29, 2012; Association of American Medical Colleges, Comments to CMS on CY 2013 OPPS Proposed Rule, August 31, 2012.

these measures and indicated that it did not believe these measures were ready for implementation in the OQR program.[5]

The statute that created the OQR program requires the secretary of the U.S. Department of Health and Human Services to develop measures that "reflect consensus among affected parties" and that are "set forth by one or more national consensus setting entities."[6] These measures are not endorsed by NQF and are opposed by multiple stakeholders with an interest in hospital quality reporting programs. **Because these measures are not endorsed by NQF and were identified for removal by MAP, they are not appropriate for the OQR program and should be removed by CMS.**

c. CMS should not add the OP-27, OP-28, OP-29, OP-30, and OP-31 measures to the OQR program.

CMS should not add the five proposed measures to the OQR program because they will unduly increase the reporting burden on hospitals and they have not all been endorsed for implementation. In its CY 2013 final rule, CMS did not propose any additional measures for inclusion in the OQR program. However, CMS is now proposing five new measures for the program:

- OP-27: influenza vaccination coverage among health care personnel (NQF #0431)
- OP-28: complications within 30 days following cataract surgery requiring additional surgical procedures (NQF #0564)
- OP-29: endoscopy/polyp surveillance: appropriate follow-up interval for normal colonoscopy in average risk patients (NQF #0658)
- OP-30: endoscopy/polyp surveillance: colonoscopy interval for patients with a history of adenomatous polyps – avoidance of inappropriate use (NQF #0659)
- OP-31: cataracts: improvement in patient's visional function within 90 days following cataract surgery (NQF #1536)

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[5]Measure Applications Partnership, Pre-Rulemaking Report: Input on Measures under Consideration by HHS for 2012 Rulemaking, Final Report, National Quality Forum, February 2012: 93.

[6]Social Security Act 1833(t)(17)(C)(i).

With the addition of these measures, the OQR program will have a total of 28 measures in FY 2016. Including new measures in the OQR program will only increase the reporting burden on hospitals and divert resources from data collection and reporting on already-existing measures. For example, the proposed OP-27 measure on provider influenza immunizations will be in the hospital inpatient quality reporting (IQR) program beginning with fiscal year (FY) 2015. America's Essential Hospitals has previously expressed concern about adding this measure to the IQR and OQR programs, as data collection and reporting would be extremely burdensome for hospitals. The numerator and denominator for this measure include not only full-time employees, but also students and volunteers in hospitals. In addition, the numerator requires data collection for those personnel who were immunized outside of the hospital. Collecting information on such a wide pool of individuals would strain the resources particularly of essential hospitals, which have low operating margins.

The four other proposed new measures are chart-abstracted measures that are not included in other hospital quality reporting programs. Reporting on these measures would also be resource intensive and burdensome for hospitals, as those with little or no experience reporting on these measures would be required to train staff and become acquainted with the reporting requirements. Ultimately, hospitals and the patients they treat will be best served by focusing on the measures that are already in the OQR program as opposed to these five additional measures.

In addition to the reporting burden, these measures have neither full NQF endorsement nor full MAP recommendation. Three of the proposed measures—OP-28, OP-29, and OP-30—have time-limited NQF endorsements, meaning that they have not been adequately field tested. Of these three measures, OP-29 and OP-30 were not recommended for inclusion in the OQR program by the MAP in its 2013 pre-rulemaking report due to implementation and data collection concerns.[7] **For these reasons, CMS should not add these measures to the OQR program.**

d. CMS should not collect patient-level data for the additional measures proposed for inclusion in the OQR program.

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[7]Measure Applications Partnership, Pre-Rulemaking Report: 2013 Recommendations on Measures under Consideration by HHS, Final Report, National Quality Forum, February 2013.

If CMS ultimately includes the four proposed chart-abstracted measures (OP-28, OP-29, OP-30, and OP-31) in the OQR program, the agency should not collect patient-level data through EHR technology for these measures. America's Essential Hospitals opposes the collection of patient-level data and believes that data collection should be limited to aggregate data. Collecting data at the patient level implicates privacy concerns, and until CMS can ensure patients' records can be securely maintained and transmitted, CMS should not collect this data. In addition, many hospitals are in the early stages of adopting EHRs and have not fully implemented these systems. Therefore, they may not have the infrastructure in place to collect patient information on these measures. **Until hospitals have fully implemented their EHR systems and CMS can properly receive and secure sensitive patient data, CMS should delay any proposal to collect patient-level data.**

4. CMS should ensure all measures in the value-based purchasing (VBP) program are endorsed by the NQF and are appropriately risk-adjusted.

CMS proposes a 12-month performance period for the catheter-associated urinary tract infection (CAUTI), central line–associated bloodstream infection (CLABSI), and surgical site infection (SSI) measures, which for FY 2016 would begin in CY 2014. CMS proposes using CY 2012 as the baseline period for the measures. While America's Essential Hospitals appreciates CMS' clarification on the performance and baseline periods for these measures, we continue to oppose any measures that are not NQF-endorsed or appropriately risk-adjusted. America's Essential Hospitals emphasized these concerns in a comment letter to the agency on the FY 2014 inpatient prospective payment system proposed rule. With the exception of the CAUTI measure, which is NQF-endorsed, **CMS should suspend these measures from the VBP program until the revised, reliability-adjusted CLABSI measure is endorsed by the NQF and the SSI measure is appropriately risk-adjusted.**

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

For CY 2014, CMS proposes to continue its CY 2013 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 or 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. CMS notes that under the proposed statutory payment rate of ASP + 6 percent, a hospital's 340B status does not affect the drug payment rate.

America's Essential Hospitals is pleased that 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.**

6. America's Essential Hospitals supports CMS' clarification of the supervision requirement for observation services.

America's Essential Hospitals supports CMS' clarification that once a beneficiary is stable and is transitioned into general supervision for observation services, there is no requirement for additional direct supervision during the service. This policy clarification will continue to improve access to outpatient services while ensuring patients receive high-quality care supervised by qualified professionals without undue burden on staff. For these reasons, America's Essential Hospitals supports the policy clarification of the supervision requirement for observation services.

7. CMS should allow hospitals to appeal or reopen intermediary payment determinations based on the date of the intermediary determination, regardless of when any predicate facts first arose.

In revising the regulations governing appeals and reopening of intermediary determinations by Medicare administrative contractors (MACs), CMS should not limit a hospital's ability to

appeal or reopen intermediary payment determinations by tying the reopening or appeal period to the predicate facts used in the intermediary determination. Instead, consistent with the regulatory language, a hospital should be permitted to appeal a payment determination within 180 days or move to reopen within three years of the payment determination, regardless of when any predicate facts may have arisen.

Generally, a provider may appeal the intermediary reimbursement decision of a MAC to the Provider Reimbursement Review Board within 180 days of the MAC's determination for the provider for a particular cost period. Alternatively, the provider may request that the determination be reopened for review within three years of the MAC's intermediary determination. In a 2013 decision, a U.S. Court of Appeals interpreted the regulation as allowing providers to appeal or reopen certain types of facts, known as predicate facts, outside of the 180-day appeal and three-year reopening window. A predicate fact is one that the MAC uses in determining a provider's reimbursement amount for a particular cost reporting period but that arose or was determined in an earlier cost reporting period. CMS disagrees with the court's interpretation of its regulation and therefore clarifies in this rule that for predicate facts used by a MAC in making a reimbursement determination, the same time limits for appeals and reopening apply. Under the revised regulation, CMS is seeking to clarify that a provider will have to appeal or request reopening of a predicate fact used by a MAC within 180 days or three years, respectively, of the date on which the predicate fact initially arose.

Making the proposed change would limit hospitals' ability to appeal reimbursement determinations if they did not challenge the predicate fact in the 180-day appeal or three-year reopening period. Predicate facts include facts used to calculate graduate medical education (GME) cost reimbursements for teaching hospitals, and restricting the time period hospitals have to appeal such determinations could adversely affect members of America's Essential Hospitals. Our members serve as teaching institutions and academic medical centers that provide training for medical and dental residents who are indispensable to the health care workforce. More than 80 percent of our members are accredited by the Accreditation Council for Graduate Medical Education and more than half are recognized as academic medical

centers by the Council of Teaching Hospitals.[8] CMS' proposed change effectively precludes a hospital from challenging payment determinations, even if the hospital appeals or moves to reopen the payment determination in a timely manner.

For example, a hospital that appeals the MAC's most recent payment determination within 180 days of the payment determination will be barred from appealing if any underlying facts used in making the payment determination arose before the 180-day period. In the case of teaching hospitals, any challenges to recent GME cost reimbursement decisions would be barred because the determination of certain facts, such as a hospital's full-time equivalent (FTE) count and FTE cap, occurred more than 180 days or three years ago. CMS' proposed change contradicts the language of the relevant regulation, which clearly states that an intermediary determination may be reopened within "three years of the date of the notice of the [intermediary decision]."[9] **For these reasons, CMS should allow hospitals to appeal intermediary determinations within 180 days of the determination itself, regardless of when any predicate facts arose.**

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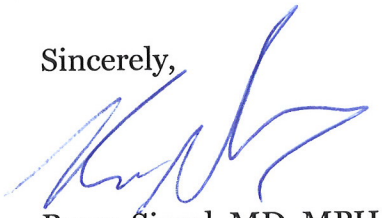
America's Essential Hospitals appreciates the opportunity to submit these comments. If you have any questions, please contact Xiaoyi Huang at 202-585-0127.

Sincerely,



Bruce Siegel, MD, MPH
President and Chief Executive Officer

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[8]Obaid 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

[9] 42 CFR § 405.1885(a).