August 31, 2015

Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Ref: CMS–1633–P: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Short Inpatient Hospital Stays; Transition for Certain Medicare Dependent, Small Rural Hospitals under the Hospital Inpatient Prospective Payment System

Dear Mr. Slavitt,

Thank you for the opportunity to submit comments on the above-captioned proposed rule. America’s Essential Hospitals appreciates and supports the Centers for Medicare & Medicaid Services’ (CMS’) work to encourage improved care delivery across the entire health care industry. In crafting outpatient payment policies, we ask CMS to consider the unique challenges inherent in caring for our nation’s most vulnerable patient populations. Filling a safety net role in their communities, essential hospitals serve patients 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, our more than 250 member hospitals fill a vital role in their communities. Our
members provide access to high-quality health care for all patients, predominantly serving patients covered by public programs and the uninsured. In fact, 21 percent of the outpatient services provided by our members are to Medicare beneficiaries, another 27 percent are to Medicaid recipients, and 24 percent are to uninsured 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 negative 3.2 percent, compared to positive 5.7 percent for all hospitals nationwide.

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 2013, the average member saw nearly 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.

Essential hospitals play a critical role in providing care to the most vulnerable members of their communities. 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 cuts in the Affordable Care Act and other hospital cuts Congress has targeted to offset federal spending, as well as policy changes that have a disproportionate impact on hospitals that treat the vulnerable.

To ensure essential hospitals have sufficient resources to continue to engage in robust quality improvement activities and are not unfairly

2Ibid.
disadvantaged for serving the most vulnerable among us, it is imperative that CMS understand the impact of its proposals on essential hospitals. To this end, we urge the agency to consider the following comments when finalizing the above-mentioned proposed rule.

1. **CMS should finalize its exception to the two-midnight policy for short inpatient stays and make other changes to the policy to preserve physician judgment and ensure patients receive the appropriate level of care in the hospital.**

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

CMS proposes to revise the policy to consider short stays (those lasting fewer than two midnights) appropriate for Medicare inpatient reimbursement if the physician believes an inpatient admission is necessary and documents this in the medical record. The reviewing entity would evaluate these short stays on a case-by-case basis to determine if the admission was reasonable and necessary. This is a step forward from the current policy, and we support this new direction. CMS now acknowledges that there may be circumstances that warrant a short inpatient stay, which is an important step in giving appropriate deference to a physician’s clinical judgment. Still, CMS notes that stays that do not cross at least one midnight will be the focus of medical review.

America’s Essential Hospitals has previously urged CMS to reverse the two-midnight policy, which has had the effect of subverting physician judgment. Instead of allowing physicians to determine the necessity of an admission based on patient-specific clinical needs, the policy places excessive authority in ex post facto judgments by auditors who are removed from the clinical decision-making process. Ultimately, allowing physicians
to base decisions on genuine medical need and not on arbitrary, time-based presumptions is critical for preserving high-quality care. The two-midnight policy has also caused confusion and added additional administrative burden for hospital staff. We applaud CMS for responding to stakeholder feedback, and we look forward to working with the agency to ensure these changes meet the desired goal of allowing the physician to be the ultimate arbiter of whether a patient should be admitted to the hospital.

For these reasons, we urge CMS to finalize and implement the change in its policy for short inpatient stays. Additionally, CMS should follow up with clear guidance to providers and other involved parties, such as reviewing entities, on how the new policy should be implemented.

CMS is also changing the medical review process by giving quality improvement organizations (QIOs)—instead of MACs and RACs—the authority to review postpayment claims for patient status. This change will take effect October 1. QIOs will be tasked with reviewing these claims and referring any denials to MACs for payment adjustment. Hospitals with high denial rates will be referred to RACs. Giving review authority to QIOs is a positive change because it limits the authority of RACs. Historically, RACs have had high overturn rates upon appeal and have less experience with the clinical process. However, CMS should regularly oversee and monitor this program during this transition, as there are a limited number of QIOs nationwide and it is imperative that they have sufficient resources to implement this rule appropriately.

America’s Essential Hospitals is also pleased that through separate guidance, CMS has extended the partial enforcement ban of the two-midnight rule until December 31. The extension means that RACs will not be conducting patient status review for the remainder of the year, and MACs will only be conducting limited reviews unrelated to patient status.

In addition to the recommendations above, CMS should consider the following recommendations associated with the two-midnight policy and patient status.

a. CMS should not have inappropriately reduced hospital payments under the Inpatient Prospective Payment System (IPPS) to offset the two-midnight policy.
In the fiscal year (FY) 2014 IPPS final rule, CMS announced that due to an expected increase in inpatient stays under the two-midnight policy, the standardized inpatient hospital payment for hospitals would be reduced by 0.2 percent. However, empirical and anecdotal evidence from hospitals suggest that since CMS announced the two-midnight policy, more stays are shifting from the inpatient to the outpatient setting.\textsuperscript{3} CMS should not have cut hospital inpatient payments when the policy was not fully implemented and the anticipated shift to inpatient stays has not actually occurred. This payment cut is especially disconcerting in light of CMS’ acknowledgement of the two-midnight policy’s shortcomings and the agency’s proposed changes to the policy. \textbf{Going forward, CMS should not subject hospitals to a prospective reduction in their inpatient or outpatient payments in anticipation of a potential rise in hospital payments due to a policy change.}

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

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

\textbf{Through separate rulemaking, CMS can modify its requirement for skilled nursing facility (SNF) coverage so the period of observation care in the hospital counts toward meeting the three-day Medicare payment requirement for patients who are admitted to the hospital.}

and then receive treatment in a SNF. Medicare will only cover SNF stays for beneficiaries who were inpatients for at least three days during the preceding hospital stay. This requirement is confusing for beneficiaries, who often don’t know their status as inpatients or outpatients. CMS has acknowledged this issue and addressed it in the context of pioneer accountable care organizations (ACOs) by introducing a waiver of the three-day SNF coverage requirement for beneficiaries in pioneer ACOs. This flexibility is a step in the right direction, but it should be extended beyond the demonstration to cover patients in all hospitals. For these reasons, CMS should deem patients under observation status to have been admitted for inpatient payment purposes after 72 hours and should count the time in observation care toward the three-day SNF coverage requirement.

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

CMS intends to expand its policy of using C-APCs by creating 9 new C-APCs in calendar year (CY) 2016, resulting in 34 total C-APCs. Under the C-APC payment policy, CMS packages payment for the primary procedure with other services that appear on the claim and were provided in association with the primary procedure. CMS pays for these adjunctive services and the primary procedure using a single C-APC payment instead of paying hospitals separately for the primary procedure and related services and supplies. 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, are also paid under the OPPS as part of C-APC payment. To mitigate the negative impact this policy may have on essential hospitals, CMS should adopt the following recommendations.

a. **CMS should revise its complexity adjustment methodology to account for the higher costs essential hospitals incur treating sicker patients.**

CMS should include a patient complexity adjustment in its C-APC proposal so the policy does not adversely affect essential hospitals, which treat sicker patients and perform more complex procedures than the average hospital. Moreover, until an appropriate adjustment is
developed and CMS better understands the potential impact of the C-APC policy on all types of hospitals, the agency should implement the proposal gradually.

To calculate the relative payment weight for the C-APC, CMS uses the geometric mean of the estimated costs on all claims for the primary procedures and all adjunctive services. Thus, a hospital receives a single global payment based on average costs across all hospitals, regardless of the cost of the primary 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 actually provided in conjunction with the primary procedure.

Such a policy has 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 puts essential hospitals at a disadvantage due to the greater number of resources needed to provide high-acuity care to clinically complex patients.

**Last year, CMS instituted a complexity adjustment under the C-APC policy that only accounts for identified instances of high-cost combinations of primary procedures. It does not account for patient characteristics.** For example, to account for complex cases in which more than one primary procedure with a J1 status indicator appears on a claim, CMS will apply a complexity adjustment and pay the hospital the next-highest C-APC amount in the clinical family. 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 sociodemographic factors, that require more resources for treatment.

Given essential hospitals’ low margins (more than half of essential hospitals have a negative operating margin, compared to 31 percent of hospitals nationally) they must find innovative and efficient ways to provide high-quality care. And data show they are effective in this, scoring slightly below the national median on the Medicare spending per beneficiary measure.5

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5Ibid.
But essential hospitals’ diverse mix of patients, in terms of clinical complexity and sociodemographic factors, complicates care and requires an intensity of resources.

Therefore, CMS should account for such cases by adjusting for patient complexity. Until CMS can implement an appropriate adjustment, CMS should gradually phase in the use of C-APCs instead of implementing the entire proposal to add 9 C-APCs for a total of 34 C-APCs in CY 2016.

b. CMS should exclude claims containing a service designated with the T status indicator from being packaged and paid under the proposed comprehensive observation services C-APC.

CMS should always pay separately for services on claims that would qualify for packaged payment under the proposed comprehensive observation service C-APC but that also contain a service marked with a T status indicator. Services with a T status indicator are major procedures, such as costly surgical procedures, that are normally paid for separately.

CMS proposes a C-APC for comprehensive observation services. For this C-APC, CMS will make a packaged payment for services on a claim when any of six designated Healthcare Common Procedure Coding System (HCPCS) codes for extended assessment and management services appear on the claim in conjunction with eight or more hours of observation services. However, CMS indicates that when a claim also contains a T status indicator for a procedure with a date of service the day of or the day before the observation services, payment for this claim will be made separately instead of through a C-APC.

America’s Essential Hospitals urges CMS to extend this exclusion of services with T status indicators to all claims appearing with such a service, notwithstanding the date the T status indicator service was performed. Making this change would result in a consistent policy, as opposed to CMS’ proposal to arbitrarily exclude only those claims where the T status indicator service was performed on the day of or the day before the patient received observation services. Services with a T status indicator are often high-cost surgical procedures, and packaging payment for these services when they are provided in conjunction with assessment and management services can result in the hospital being insufficiently
compensated for the amount of resources employed to treat a patient. For example, costly cardiac procedures, such as diagnostic cardiac catheterization and level 1 pacemaker procedures, are T procedures that, if performed outside of CMS' designated window, would be packaged into the C-APC payment. Even if such a service were performed just two days before the patient received observation services, CMS would pay the hospital the C-APC amount, while the hospital would be paid separately for the T service if it is performed one day before the observation services. To ensure adequate reimbursement for hospitals performing these high-cost services, CMS should exclude all claims that list services with a T-status indicator from being paid under the comprehensive observation services C-APC.

c. CMS should not adopt a claims-based modifier for services adjunctive to J1 primary services.

CMS should not finalize its proposal to use a claims-based modifier to identify adjunctive services, which are services provided to support the delivery of a primary service with a J1 status indicator. Requiring hospitals to report this modifier would be administratively burdensome and difficult to implement. CMS is proposing to require hospitals to report a HCPCS modifier with every code for outpatient hospital services that is adjunctive to a comprehensive service but that is billed on a different claim. This modifier would be reported on hospitals’ UB-04 form (CMS form 1450) for outpatient services. CMS’ rationale for this modifier is to gather information on adjunctive services that should be packaged into a C-APC with the primary service but are not packaged because they do not appear on the same claim.

America’s Essential Hospitals is 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. The modifier would require hospital staff to identify whether a service is adjunctive to a comprehensive service. But there are more than 800 J1 procedures that CMS lists in the addendum to the proposed rule, and hospitals will be required to isolate each occurrence of a service on a different claim that is adjunctive to one of these 800 J1 procedures. Therefore, it would be extremely cumbersome for billing personnel to adapt their systems to identify which services are considered adjunctive to a comprehensive
primary service, particularly given the lack of clarity around what constitutes an adjunctive service.

Furthermore, the proposal is lacking in clear guidance as to how far back a hospital must look to identify services that may be adjunctive to the primary service. Requiring hospitals to report this modifier would take a significant investment of time and resources. And coupled with other modifiers that CMS requires hospital to report, this addition would consume hospital resources and time for training and implementation. For these reasons, CMS should not require hospitals to use the HCPCS modifier to identify services adjunctive to a comprehensive service.

3. **CMS should not reduce outpatient payment rates to compensate for incorrect calculations associated with its CY 2014 laboratory packaging policy.**

CMS proposes to apply a 2 percent reduction to the conversion factor, which results in a negative OPPS payment update of 0.1 percent for CY 2016. CMS is proposing this reduction to compensate for overpaying for clinical diagnostic laboratory tests in CY 2014. In that year, CMS instituted a new policy to package laboratory payments and used erroneous assumptions and calculations in projecting the impact of the policy.

However, the 2 percent reduction in the payment update, coupled with the negative impact of other proposals in this rule, will undermine essential hospitals’ ability to fulfil their mission to provide quality care to all patients, including the most vulnerable. To prevent further reductions in payments to essential hospitals, CMS should not institute this negative payment update for CY 2016, which is a result of the agency’s own erroneous calculations two years ago regarding the extent to which laboratory services would be packaged.

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 hospitals are giving. 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 remove one measure from the OQR Program beginning with the CY 2017 payment determination. The agency also proposes to add two measures—one for the CY 2018 payment determination and one for the CY 2019 payment determination. America’s Essential Hospitals supports removing measures that no longer accurately capture distinctions in quality of care and do not align with current clinical guidelines. Removing these measures reduces the administrative burden on hospitals and ensures the OQR measure set is up to date. 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 remove the OP-15 measure from the OQR Program, as it does not align with current clinical guidelines and is not appropriate for measuring quality at the facility level.

CMS proposes to remove the OP-15 measure (Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache) beginning with the CY 2017 payment determination. Since the adoption of this measure in the CY 2011 OPPS final rule, CMS has deferred public reporting and continued to evaluate the measure due to stakeholder concerns that the measure fails to represent appropriateness or efficiency accurately. CMS refined the measure based on comments, but it remains inconsistent with the most updated clinical guidelines and practice. America’s Essential Hospitals supports the agency’s decision to exclude this measure from the OQR Program and encourages CMS to finalize this proposal.

b. CMS should add the OP-33 measure to the OQR Program to ensure appropriate use of external beam radiotherapy (EBRT) and prevent the overuse of radiation therapy.

CMS proposes to add the OP-33 measure (EBRT for Bone Metastases [NQF #1822]) to the OQR Program for the CY 2018 payment determination and subsequent years. This measure assesses the percentage of patients (all payer) with painful bone metastases and no history of previous radiation who receive EBRT with an acceptable dosing schedule
based on the clinical guideline. CMS states that the measure will address concerns associated with unnecessary exposure to radiation and a desire for shorter and less painful treatment options. America’s Essential Hospitals supports the addition OP-33 to align provider practices and reduce treatment variation. However, CMS should monitor this measure, along with available data, to ensure the measure reflects the most effective schedule of dosing for relieving pain from bone metastases, patient preferences, and time and cost effectiveness.

c. CMS should refine the OP-34 measure, clarify the responsibilities of the receiving facility, and delay inclusion of the measure in the OQR Program to allow providers adequate time to become familiar with implementation protocol and tools related to the measure.

CMS proposes to add the OP-34 measure (Emergency Department Transfer Communication [EDTC] [NQF #0291]) for the CY 2019 payment determination. The EDTC measure captures the percentage of patients transferred to another health care facility whose medical record documentation indicated that administrative and clinical information was communicated to the receiving facility in an appropriate time frame.

As proposed, the EDTC measure includes seven subcomponents: administrative data, patient information, vital signs, medication, physician information, nursing information, and procedure and test results. These subcomponents are further comprised of a total of 27 elements. A hospital would only receive a perfect score of “7” if the hospital reports a “yes” for all elements, demonstrating the data were recorded and communicated to the receiving facility.

America’s Essential Hospitals supports the effective and timely communication of a patient’s clinical status and other relevant information at the time of transfer from the hospital to support appropriate continuity of care. However, the methodology of this measure is an all-or-nothing approach in which a hospital that theoretically reports and properly communicates 26 of the 27 elements would receive a total score of zero. In addition, CMS estimates three to six months will be required for hospitals to familiarize themselves with the implementation protocol and tools related to the EDTC measure. However, the basis for this implementation

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time frame is unclear. **We urge CMS to delay inclusion of this measure, beyond the proposed CY 2019 implementation date, due to the uncertainty of time and resources required of hospitals to put the processes and procedures in place to collect the information and report on this measure.**

Furthermore, it is unclear to what extent, if at all, the receiving facility would share responsibility with the transferring facility for confirming receipt of information. CMS should provide further guidance as to the format by which a transferring facility is required to communicate the elements of this measure to the receiving facility to ensure uniformity in the application of the measure. **CMS should seek input from both transferring and receiving providers and collaborate on what patient information is most important to a receiving hospital and how best to communicate such information in a timely manner, thereby improving care coordination.**

**d. CMS should finalize its proposed change to the time frame on which CMS bases annual payment update (APU) determinations for the OQR Program.**

Currently, CMS bases its APU determinations on chart-abstracted data from the third quarter two years prior to the payment determination through the second quarter of the year prior. For example, APU determinations for the CY 2016 OQR Program are based on data from quarter three of 2014 through quarter two of 2015. However, as data from the second quarter are due November 1, hospitals and CMS have less than two months between the time data are submitted for validation and the beginning of the new payments based on these data (January 1).

CMS is now proposing to base APU determinations on data from the second quarter two years prior through the first quarter of the year prior. Since the quarter-one deadline for submission is August 1, hospitals would have additional time to review APU determinations before they are implemented. **America’s Essential Hospitals supports CMS’ change to the time frame, which will ease the burden on hospitals and allow them additional time to review APU determinations prior to their impact on payments. For these reasons, CMS should finalize this proposal.**
5. CMS should finalize its proposed statutory default payment for separately payable drugs and biologicals.

For CY 2016, CMS proposes to continue its 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. 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 Beth Feldpush, DrPH, senior vice president of policy and advocacy, at 202-585-0111.