AMERICA'S ESSENTIAL HOSPITALS

September 6, 2016

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 Ave. SW
Washington, DC 20201

Ref: CMS-1656-P: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Electronic Health Record (EHR) Incentive Programs; Payment to Certain Off-Campus Outpatient Departments of a Provider; Hospital Value-Based Purchasing (VBP) Program

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 improve the delivery of high-quality, integrated health care across the continuum. We are concerned that certain provisions of the Affordable Care Act (ACA) and recently enacted laws have a disproportionately negative financial impact on essential hospitals—those that commit to serving low-income and other vulnerable patients—and run counter to the concept of integrated, coordinated health care. In fact, CMS' proposed implementation of the Bipartisan Budget Act of 2015 (BBA) will drastically limit the ability of essential hospitals to expand access to the most vulnerable populations and goes beyond the scope of the legislative text. With these considerations in mind, America's Essential Hospitals asks CMS, when finalizing this rule, to consider the unique challenges inherent in caring for our complex patient populations.

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. Filling a vital role in their communities, our nearly 275 member hospitals provide a disproportionate share of the nation's uncompensated care and devote approximately half of their inpatient and outpatient care to Medicaid or uninsured patients. Essential hospitals treat more patients who are dually eligible for Medicare and Medicaid than the average hospital. These patients often have multiple comorbidities and chronic conditions and are among the most difficult to treat. More than a third of patients at

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essential hospitals are racial or ethnic minorities who rely on the culturally and linguistically competent care that only essential hospitals can provide. Our members provide this care while operating on margins substantially lower than the rest of the hospital field: zero percent in aggregate compared with 8.3 percent for all hospitals nationwide.[1] Through their integrated health systems, members of America's Essential Hospitals offer a full range of primary through quaternary care, including trauma care, outpatient care in their ambulatory clinics, public health services, mental health services, substance abuse services, and wraparound services critical to vulnerable patients.

In particular, essential hospitals play a vital role in providing ambulatory care to their communities. The average member operates a network of more than 20 ambulatory care sites. And in 2014, the average member saw more than three times as many non-emergency outpatient visits as other acute-care hospitals nationwide. Our members provide comprehensive ambulatory care through networks of hospital-based clinics that include onsite features—radiology, laboratory, and pharmacy services, for example—that freestanding physician offices typically do not offer. Our members' ambulatory networks also offer behavioral health services, interpreters, and patient advocates who can access support programs for patients with complex medical and social needs.

The high cost of providing complex care to low-income and uninsured patients leaves our hospitals with limited resources, driving 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 cuts to hospitals in the ACA and other hospital cuts Congress has targeted to offset federal spending.

To ensure our members have sufficient resources to continue to expand access and are not unfairly disadvantaged for serving the most vulnerable among us, CMS should adopt the following recommendations when finalizing the above-mentioned proposed rule.

1. **CMS should delay implementation of Section 603 of the BBA by at least one year to establish reasonable policies that align with the intent of the BBA, as well as offer sufficient time for hospitals to make necessary system adjustments.**

As mandated by Section 603 of the BBA, CMS will discontinue paying certain off-campus, provider-based departments (PBDs) under the Outpatient Prospective Payment System (OPPS) on January 1, 2017. The BBA instructs CMS to pay these PBDs under another Part B "applicable payment system" instead of the OPPS. The BBA defines which PBDs would be affected by the law and specifically exempts other types of PBDs from changes in reimbursement.

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[1]Landry C, Ramiah K, Rangarao S, Roberson B. *2014 Essential Data, Our Hospitals, Our Patients; Results of America's Essential Hospitals 2014 Annual Member Characteristics Survey.* America's Essential Hospitals. June 2016. http://essentialdata.info/. Accessed August 10, 2016.

Given essential hospitals' expansive networks of ambulatory care in otherwise underserved communities, the BBA will have a pronounced negative impact on patients of essential hospitals. If implemented as proposed in the BBA, cuts in outpatient Medicare payments could reduce payments for many services by about 50 percent and, in some cases, by close to 90 percent. However, although the statute clearly references the continuation of hospital payments, for calendar year (CY) 2017, CMS proposes that no facility payment will be made directly to the hospital's off-campus PBD. This proposal is unconscionable. And, for hospitals operating on narrow (often negative) margins, these cuts are unsustainable. The patients seeking care at off-campus PBDs of essential hospitals tend to be lower income and racial and ethnic minorities, and they are more likely to be uninsured. Clinics of essential hospitals often fill a void by providing the only source of primary and specialty care in their communities. Excessively burdensome and restrictive policies on PBDs of essential hospitals will undoubtedly have downstream effects, including on patient access.

Due to the magnitude of Section 603's impact on hospitals and patient access, CMS should give appropriate consideration to the negative consequences of its proposals and the difficulty providers will face in adapting to its proposals on a short timeframe. **Specifically, we call on the agency to delay the implementation of Section 603 for at least one year.** In its current form, the proposal oversteps the boundaries set out by Congress in the BBA and also puts forth policies that will be impractical for hospitals to implement on such short notice. Hospitals will have a mere 60-day period to make cumbersome changes to their billing systems and to prepare for the impact of Section 603 on their reimbursement. CMS should delay implementation by at least one year so it can thoroughly consider stakeholder feedback and establish policies that carry out Section 603 as Congress intended. This delay would not be without precedent, as CMS has on numerous occasions delayed the implementation date of new payment systems required by law. To name just a few examples, CMS has previously delayed the implementation of the OPPS, the ambulance fee schedule, and most recently, the market-based payment system for the clinical laboratory fee schedule. Below, we provide additional recommendations for CMS to consider for future implementation of Section 603.

2. CMS should implement Section 603 of the BBA consistent with the legislative text and minimize the adverse impact its policies will have on patient access.

In drafting the BBA, Congress left many specifics of Section 603 implementation for CMS to clarify through the rulemaking process. However, in its interpretation, the agency has unnecessarily expanded the law's scope, and this will compound the harm to essential hospitals and the vulnerable patients they serve. For example, CMS has proposed that PBDs that relocate or expand services would lose their grandfathered status, a limitation the BBA neither contemplated nor required. In addition, the agency suggests billing processes that will be administratively burdensome, costly, and time-consuming for hospitals to implement.

By going beyond the legislative text of the BBA, CMS has interpreted the law in a way that will adversely impact patient access by limiting incentives for essential hospitals to bring health care into underserved communities. Essential hospitals are the only

providers willing to take on the financial risk of providing comprehensive care to low-income patients, including the uninsured and dually eligible beneficiaries. These clinics enable hospitals to expand access for vulnerable patients in communities with no other options for both basic and complex health care needs. PBDs of essential hospitals often are the only clinics in low-income communities that provide the full range of primary and specialty services. The proposals in the rule are an added obstacle that will only frustrate the ability of essential hospitals to continue to play this vital role in their communities. **We urge CMS to apply Section 603 in a way that is consistent with the legislative text and that will protect patient access by taking into account these considerations:**

a. CMS should finalize the exception for dedicated emergency departments, PBDs within 250 yards of remote locations, and on-campus PBDs.

In the proposed rule, CMS describes the types of facilities that would be excepted (or grandfathered) from the provisions of Section 603 and continue to receive OPPS reimbursement. Other than off-campus PBDs that were furnishing services before the date of enactment, the BBA specifically mentions dedicated emergency departments, PBDs within 250 yards of a remote location, and on-campus PBDs. **CMS should finalize its proposal to except all services provided at these types of facilities, as they were explicitly delineated in Section 603 of the BBA.**

b. CMS should classify off-campus PBDs that were billing for services furnished before the date of enactment as excepted PBDs that are unaffected by Section 603, even if they expand services.

CMS notes, as required by Section 603, that off-campus PBDs that were billing for services provided before November 2, 2015, would be "excepted" from reduced reimbursement. However, CMS adds a distinction not found in the text of the BBA: It would categorize items and services provided at these PBDs as services provided before or after the date of enactment. Under CMS' proposal, excepted PBDs will only receive OPPS payment for items and services that were provided by the PBD before the BBA. If the PBD were to expand services beyond the types of services provided pre-enactment, these new services would be non-excepted and reimbursed at a rate other than OPPS. Effectively, this creates two categories of services at PBDs: those that will receive OPPS reimbursement and any new services that will receive payment under another Part B applicable payment system. This categorization of excepted and non-excepted services at a given PBD is inconsistent with the text of the BBA. Furthermore, it is a short-sighted policy proposal that fails to account for the changing needs of hospitals' communities and hospitals' long-term plans to address these changing needs. **CMS should withdraw this proposal and clarify that, as defined in the BBA, any PBD that was billing for services provided before November 2, 2015, is an excepted PBD for all of the services it provides.**

In support of its proposal to carve out certain types of items and services from the exception, CMS argues that the BBA "applies to off-campus PBDs as they existed at the

time of enactment."[2] But the statute neither states nor implies that this is the case. Section 603, titled "Treatment of Off-Campus Outpatient Departments of a Provider," clearly states that for purposes of Section 603, "the term 'off-campus outpatient department of a provider' shall not include a department of a provider (as so defined) that was billing" for outpatient department services furnished pre-enactment.[3] In other words, a PBD that was billing for services prior to the date of enactment is completely carved out of the definition of "off-campus outpatient department of a provider." Section 603 only reduces reimbursement to applicable items and services provided at "off-campus outpatient departments of a provider," and by carving out existing PBDs from the definition, the BBA is clear that these PBDs and services provided at these PBDs are unaffected by its provisions. Additionally, nowhere in the text of the BBA can any language be found that suggests that these PBDs are excepted for only those services being provided pre-enactment.

CMS references the provider-based regulations to support its claim that a provider-based department should be excepted only as it existed at the time of enactment. The regulatory language that CMS cites defines a PBD as including the physical facility as well as the personnel and equipment that are needed to provide services at the PBD. However, the provider-based rules do not limit the scope of services that can be provided by a PBD. In fact, in rulemaking on the provider-based requirements, CMS previously noted that "the provider-based rules do not apply to specific services; rather, these rules apply to facilities as a whole."[4]

CMS states that its rationale for restricting the expansion of services at PBDs is to prevent the possibility of hospitals purchasing freestanding clinics and adding the physicians to their existing off-campus PBDs. However, Section 603 was intended to prevent new practices from being created or acquired, not to prevent the expansion of existing ones. Moreover, essential hospitals have many reasons why they might need to expand services and there are many valid policy reasons to allow PBDs to change their service mix. Most important, as the needs and composition of communities change, the types of services essential hospitals need to provide through their PBDs also change. Essential hospitals, already operating on narrow, often negative, margins, are motivated solely by the needs of their patients—patients who do not have access to other providers in their communities. As directed by the ACA, they constantly assess the needs of their communities and they engage in population health programs that aim to bring health care services into communities that previously lacked access. Ambulatory networks are an indispensable part of integrated hospital systems' long-term vision to address the needs of their community at large, particularly when they serve vulnerable patients who live in underserved areas with limited access to transportation. By allowing PBDs of hospitals to re-evaluate the needs of their communities and add or remove services as appropriate, CMS will be protecting patient access and helping to ensure care where it is needed.

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[2]Centers for Medicare & Medicaid Services. Calendar Year 2017 Outpatient Prospective Payment System Proposed Rule. 81 Fed. Reg. 45604, 45684 (July 14, 2016).

[3]Section 603 of Bipartisan Budget Act of 2015. Pub. L. 114-74, codified as Social Security Act §1833(t)(21)(B)(ii).

[4]Centers for Medicare & Medicaid Services. Fiscal Year 2003 Inpatient Prospective Payment System Final Rule. 67 Fed. Reg. 49982, 50088 (August 1, 2002).

c. CMS should change its proposal restricting relocation and should permit excepted PBDs to maintain their excepted status notwithstanding relocation.

CMS should allow PBDs to retain their excepted status, even if they relocate, as long as they continue to meet the provider-based requirements. Using a similar line of reasoning to that used to justify the limitation on the expansion of types of services, the agency also proposes that excepted off-campus PBDs that relocate will lose their excepted status. CMS says that because it believes the PBDs should only be excepted as they were at the time of enactment, if they relocate they are no longer the same PBD.

However, there are many external forces that could compel a hospital to relocate a clinic. For one, when a provider's lease for a PBD expires, it might find the renewal terms unsustainable, particularly for a PBD of an essential hospital with negative margins. As landlords realize that CMS policy effectively makes a PDB a captive audience, they might begin to raise the rent. While any reasonable business facing such unfavorable economic conditions would consider relocation as a response, a PBD might simply close, given the lack of a financially viable alternative under the proposed relocation policy. There are many other possible reasons for relocation beyond a provider's control, such as a building being closed down for reconstruction or demolition, local zoning changes or ordinances, or other state and local laws. Hospitals in California, for example, must abide by zoning regulations governing seismic activity and might be required to relocate if it is determined that a facility is at high risk of damage from seismic activity. Hospitals must also respond to damage caused by natural disasters, such as tornadoes, hurricanes, floods, and earthquakes. If a PBD in an area affected by a natural disaster needs to close its doors, it will have no choice but to relocate to prevent a disruption in access for its patients. CMS' prohibition on relocation is guided by the agency's belief that hospitals are motivated only by financial considerations. But as these examples show, there are many reasons a provider might have to relocate that fall outside the agency's narrow scenario.

There is precedent for allowing for the relocation of provider-based facilities, such as in the context of critical access hospitals (CAHs) that were grandfathered as "necessary providers" (a designation that allows a CAH to circumvent certain geographical requirements), as well as their associated off-campus, provider-based departments. While the Medicare Modernization Act of 2003 eliminated the necessary provider designation for CAHs, those with necessary provider designation that existed before January 1, 2006, were grandfathered. CMS has indicated in rulemaking that CAHs and their provider-based departments that are grandfathered may relocate without losing their grandfathered status.[5] As CMS noted in the preamble to the calendar year 2008 OPPS final rule, in response to a question on relocation of PBDs of grandfathered CAHs, the agency "believe[s] it would be reasonable for a CAH to be able to move its facility . . . ." Thus, CMS would be consistent in also allowing PBDs of acute care hospitals to relocate and maintain their excepted status under Section 603.

[5]Centers for Medicare & Medicaid Services. Calendar Year 2008 Outpatient Prospective Payment System Final Rule, 72 Fed. Reg. 66580, 66882 (November 27, 2007).

d. CMS should revise its proposal so non-excepted PBDs retain their excepted status if they change ownership.

CMS' proposal regarding changes of ownership is to allow a PBD to maintain its excepted status if the main provider that owns the PBD changes ownership and the new main provider accepts the existing Medicare provider agreement. In scenarios where the main provider does not change ownership but only an individual PBD changes ownership, CMS states that the PBD would lose its excepted status. **We request that CMS extend the policy on changes of ownership to circumstances in which an individual PBD changes ownership.** It is not uncommon for provider-based facilities to change hands over time for various reasons. For example, a hospital that finds it unsustainable to continue operating an off-campus PBD for financial or other reasons might decide to sell that particular PBD. But if the loss of excepted status makes the PDB unattractive to potential buyers, the hospital might close it. In such a case, patients in the community would lose access to essential outpatient services. Because these excepted PBDs that change ownership already operated before the date of enactment and would not be newly created, they should remain excepted.

e. CMS should work to accurately capture data to use for determining which off-campus PBDs are excepted under Section 603.

CMS acknowledges the shortcomings of using enrollment information to identify services provided at PBDs that are excepted. **CMS should work with stakeholders during a delay of implementation to identify the least burdensome and most accurate method of determining which PBDs were billing for services provided before the date of enactment.** Hospital enrollment information is incomplete because the provider enrollment, chain, and ownership system (PECOS) does not update in real time and, thus, does not accurately reflect all enrolled locations on a given date. For example, if CMS were to look at PBDs that appeared in PECOS as of November 1, 2015, there might be PBDs for which an amended enrollment form was submitted before November 1 but that did not appear in PECOS on November 1 due to the time lag in PECOS. Additionally, the date of enrollment does not directly match the date when the PBD begins providing services, and the latter would be a more accurate representation of which PBDs should be excepted. **Because of the obvious ramifications for a PBD being classified as excepted or non-excepted, CMS should ensure it has an accurate method of identifying excepted PBDs before implementing Section 603.**

f. CMS should ensure that PBDs are adequately reimbursed for the cost of providing services to patients.

For CY 2017, CMS proposes that it will make no facility payment to non-excepted PBDs. CMS proposes instead that the physician performing the service will bill under the Medicare Physician Fee Schedule (MPFS) and receive the non-facility rate, which is the higher rate that a physician receives in a freestanding office. **We strongly urge CMS to pay PBDs a facility payment that will adequately cover the costs of providing services to their patients.** While CMS says it is not currently able to pay hospitals under the MPFS, CMS already pays hospitals for specified services billed on

institutional claim forms under the MPFS, including mammography and outpatient therapy services. Furthermore, the lack of a facility payment is contrary to the legislative text requiring PBD payment, which clearly indicates that "payments for applicable items and services furnished by an off-campus outpatient department of a provider shall be made"[6] under the applicable Part B payment system.

We urge CMS to adopt a payment mechanism and payment rates that will adequately account for the higher acuity of patients treated in PBDs compared to physician offices, and the requisite resources, staff, and capabilities necessary to treat these patients in a PBD. PBDs of essential hospitals in particular are able to offer culturally and linguistically competent care tailored to the most vulnerable patients in their communities. Whether due to the clinical complexity of their patients or the additional resources needed to provide translators and wrap-around services, essential hospitals incur higher costs in treating their patients. **Given these factors, we urge CMS to comply with the intent of the BBA by paying PBDs a facility payment, at a minimum, to ensure access for patients of essential hospitals.**

g. CMS should ensure continuity in hospital billing and minimal disruption to hospital billing systems.

CMS states that it is looking into alternative ways for hospitals to bill for non-excepted, off-campus PBD services in CY 2018 onwards. Hospitals currently bill Medicare for hospital-based services on the UB-04 (CMS-1450) claim form. As CMS transitions payment for off-campus PBD services to another applicable payment system, such as the MPFS, hospitals should be permitted to continue submitting claims on the UB-04 form. We urge CMS to ensure continuity in hospital workflows and processes and to minimize any unnecessary burden resulting from a change in billing. **Hospitals are accustomed to using the UB-04 form, and notwithstanding any payment changes, should be able to continue to submit the UB-04 form for hospital claims to capture the charges associated with providing a service.**

Hospitals use the UB-04 form to submit claims not just to Medicare, but to other payers. The UB-04 form allows a hospital to bill for services and also to report additional data through the use of occurrence codes and condition codes. Billing systems for other providers, such as physician offices, do not contain the same level of detail, and they also do not allow hospitals to bill for unique services that are offered exclusively in the PBD setting. Changing the billing form for hospital claims will necessitate systemwide changes, including the financial investment and time required for information technology upgrades and staff training. **To avoid disruption to existing billing systems, CMS should preserve the current billing process for hospitals. If CMS envisions any changes to hospital billing, the agency should accommodate providers by providing sufficient time and resources to ensure a successful transition.**

[6]Section 603 of Bipartisan Budget Act of 2015. Pub. L. 114-74, codified as Social Security Act §1833(t)(21)(C).

h. CMS should ensure costs and charges for services furnished at non-excepted PBDs appear on the hospital's Medicare cost report.

We also urge CMS to maintain current Medicare cost reporting procedures for PBDs and to refrain from changing the placement of costs, charges, and revenues associated with PBDs on a hospital's cost report. Section 603 affects only the reimbursement methodology for non-excepted PBDs and does not affect the status of these departments as entities of the hospital, which CMS makes clear in the proposed rule by stating that these departments continue as provider-based facilities. For hospitals' cost reporting purposes, it is important that costs and charges associated with non-excepted PBDs continue to appear on a reimbursable line of the cost report, as is currently the case. This is important for numerous reasons, including hospital uniform charge requirements and to accurately calculate hospitalwide costs and charges to be used in CMS' cost apportionment methodology. **As CMS considers changes to billing, we urge the agency to revise cost reporting procedures and instructions to ensure continuity in current cost reporting practices for off-campus PBDs.**

3. 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 25 new C-APCs in CY 2017, resulting in 62 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 visits and evaluations provided in conjunction with the primary service. Payments that are typically not made under the OPPS but under a separate fee schedule, including payment for durable medical equipment, also are paid under the OPPS as part of C-APC payment. **To mitigate the potential negative impact of this policy 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 performing complex procedures and 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. 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 adversely affects essential hospitals. Certain types of tests or diagnostic procedures might 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.

CMS uses 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, they must find innovative and efficient ways to provide high-quality care. Data show they are effective at this, scoring slightly below the national median on the Medicare spending per beneficiary measure.[7] But essential hospitals' diverse mix of patients, in terms of clinical complexity and sociodemographic factors, complicates care and requires intense resources. **Therefore, CMS should account for these factors by adjusting for patient complexity in the C-APC methodology.**

In addition to adjusting for patient complexity, CMS should make revisions to its complexity adjustment methodology that will more accurately reimburse hospitals for performing certain costly procedures. **First, CMS should identify additional procedure combinations that should qualify for a complexity adjustment, including procedures with status indicators S or T that are performed in conjunction with a primary procedure.** Procedures with S or T status indicators are major procedures, such as costly surgical procedures, that are normally paid for separately. However, under the C-APC methodology, payment for these services is packaged into the C-APC when these services appear on a claim with a J1 primary procedure. CMS evaluates claims with combinations of J1 or J2 procedures or add-on codes with status indicator N to determine if the combination of procedures is substantially costlier than the other services in the C-APC. The agency does not evaluate other types of procedures for complexity adjustments, and we urge the agency to do so or it will potentially be underpaying hospitals for the cost of performing resource-intensive procedures in conjunction with the primary procedure on the claim.

CMS should also move a C-APC to the next highest C-APC in the clinical family when there is a violation of the two-times rule in the receiving C-APC. Under current policy, when a combination of services on a claim meets the criteria for a complexity adjustment, it is paid at the rate for the next highest C-APC (the "receiving C-APC") in

[7]Landry C, Ramiah K, Rangarao S, Roberson B. *2014 Essential Data, Our Hospitals, Our Patients; Results of America's Essential Hospitals 2014 Annual Member Characteristics Survey.* America's Essential Hospitals. June 2016. http://essentialdata.info/. Accessed August 10, 2016.

the clinical family. However, if there is a violation of the two-times rule when the code combination is moved to the receiving C-APC, CMS does not apply the complexity adjustment. A procedure violates the two-times rule when its cost is more than twice that of the lowest-cost procedure in the C-APC. CMS proposes to remove the requirement that there not be a violation of the two-times rule for the complexity adjustment to apply. **We agree with this change, but we also ask CMS to move the C-APC to the next higher level—that is, two levels higher than the originating C-APC—when there is a violation of the two-times rule in the receiving C-APC.** Because the costs of the procedure combination are significantly higher than other procedures in the C-APC, CMS should move the C-APC one level higher to ensure adequate reimbursement for the costs of furnishing all of the services in question. By adopting these recommendations, CMS will ensure that hospitals have sufficient resources to continue providing cutting-edge services to treat complex conditions.

b. CMS should discontinue its policy of requiring hospitals to carve out time spent performing certain services from reported observation hours.

CMS' policy on the reporting of observation hours, as stated in the Medicare Claims Processing Manual, requires hospitals to carve out of observation hours any time spent performing diagnostic or therapeutic services that require active monitoring. For example, if a hospital has placed a patient under observation but during this time performs a colonoscopy that requires active monitoring, the hospital must carve out the time associated with the colonoscopy from the time reported as observation hours. Under the C-APC for comprehensive observation services that CMS finalized last year, any adjunctive services appearing on a claim with a J2 status indicator are treated as related services that are packaged for payment purposes. Because all services—with limited exceptions—are now paid under the same C-APC and are treated as adjunctive to the observation services, it is unreasonable and redundant to require hospitals to continue to carve this time out from observation hours. Determining the amount of time to carve out from observation hours is a cumbersome process for hospitals that is no longer necessary. **For this reason, we urge CMS to revise its billing policy to be consistent with the C-APC for comprehensive observation services by not requiring hospitals to carve out time for these procedures.**

4. CMS should finalize its policies to ease the burden on providers in the Medicare Electronic Health Records (EHR) Incentive Program and continue to identify policies to provide much-needed flexibility to providers.

CMS proposes changes to the Medicare EHR Incentive Program for CYs 2017 and 2018 that will provide limited flexibility for eligible hospitals (EHs) in the program. These proposals are an encouraging step and an acknowledgement by the agency that EHs still face obstacles to the meaningful use of health information technology, particularly on measures that have unrealistically high thresholds and depend on circumstances outside of providers' direct control. **CMS should finalize these proposals and also extend them to the Medicaid EHR Incentive Program, because they offer much-needed relief to providers struggling with stringent program requirements.**

a. CMS should finalize a 90-day reporting period for CY 2016 and should accommodate providers who are unable to benefit from the 90-day reporting period in 2016 due to the short timeframe between final rule publication and the end of CY 2016.

We are pleased CMS has responded to provider feedback by proposing a 90-day reporting period in 2016. The flexibility of a 90-day reporting period will be critical in 2016, as all providers are required to move to modified Stage 2 objectives regardless of which stage they attested to in 2015. Many of the modified Stage 2 objectives, such as electronic prescribing, were not Stage 1 measures for hospitals, so hospitals will benefit from the additional preparation time resulting from a shorter reporting period. The shorter reporting period will allow these hospitals time to adjust to the more stringent requirements of Stage 2 and to make system changes necessitated by new measures and thresholds. However, by the time CMS finalizes the OPPS rule, EHs will have approximately 60 days until the end of CY 2016. This will be a problem for those EHs that have not yet begun their reporting period. **Accordingly, CMS should promptly indicate through other guidance its intention to finalize this policy and also provide any needed accommodations for these EHs, including allowing the 90-day reporting period to extend into the beginning of CY 2017.**

b. CMS should finalize its revised measure thresholds for Stages 2 and 3.

CMS should finalize the proposed lower thresholds for measures in 2017 and 2018. For modified Stage 2 in CY 2017, CMS proposes to lower the threshold for the measure requiring an EH's patients to view, download, or transmit their health information from 5 percent to one patient. CMS also proposes the same change to the threshold for this measure in CYs 2017 and 2018 for EHs attesting to Stage 3 requirements. America's Essential Hospitals has previously emphasized the importance of flexibility on measures that depend on patient action. These measures are particularly difficult for essential hospitals due to their vulnerable patient populations who may have lower access to and less knowledge of how to use information technology, and providers should not be penalized for failing to meet thresholds when performance on a measure is outside of their control.

CMS proposes to lower the secure messaging measure threshold, from 25 percent to 5 percent. Additionally, the agency proposes to lower thresholds for measures involving health information exchange, such as the summary of care measure from 50 percent to 10 percent. **These proposals are in line with America's Essential Hospitals' previous recommendations, and we encourage CMS to finalize the lower thresholds.**

c. CMS should extend the measure changes to the Medicaid EHR Incentive Program to keep the programs aligned and prevent provider confusion.

As noted above, CMS has made multiple changes to the Medicare EHR Incentive Program, including the removal of topped out objectives and the lowering of measure thresholds. CMS states in the rule that these changes will only apply to the Medicare EHR Incentive Program and not to providers attesting to Medicaid EHR Incentive Program requirements. As CMS notes, state agencies may require additional time and

assistance to implement changes to the Medicaid side of the program. Therefore, CMS should work with states to provide necessary flexibility that will enable them to make the required changes. Maintaining separate requirements for providers attesting to the Medicaid requirements is unnecessarily confusing and burdensome, especially because the vast majority of hospitals participate in both the Medicaid and Medicare EHR Incentive Programs. By offering flexibility in one program but not in the other, CMS is essentially creating two distinct tracks with different requirements, and negating any benefit of reduced thresholds on the Medicare side of the program. CMS can work with states to provide technical assistance and support that will facilitate any required system and process changes. Additionally, CMS could provide a 90-day reporting period in 2017, which would give states and providers additional time to make necessary changes in the event of any challenges they may encounter. **To keep the EHR Incentive Programs aligned for EHs, CMS should adopt the same changes to the Medicaid EHR Incentive Program as it proposes for the Medicare EHR Incentive Program.**

We support CMS' aim to encourage the advanced use of EHRs through the EHR Incentive Programs. EHRs should be used to help providers improve the patient care they deliver without overburdening their systems and infrastructures. However, we have previously expressed our concerns that some Stage 3 requirements would impose excessive burdens on providers instead of incorporating meaningful metrics to improve the provision of health care and the provider-patient relationship. The Stage 3 provisions previously finalized merely build on many flawed elements of the existing program, simply raising thresholds for measures already demonstrated to be unfeasible to achieve. We are pleased to see that CMS has acknowledged the unrealistic thresholds and has lowered thresholds for difficult measures, such as those involving patient access and health information exchange. **We call on CMS to finalize its lower thresholds and 90-day reporting period and to continue to evaluate provider performance in the EHR Incentive Programs and make necessary future adjustments, as needed.**

5. **CMS should finalize its proposal to remove the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) pain management dimension from the hospital Value-Based Purchasing (VBP) Program.**

America's Essential Hospitals understands that patient-centered care improves patient outcomes and satisfaction. In 2006, CMS implemented the HCAHPS survey as one method of formally recognizing that patient experience is central to health care, shifting quality metrics from the provider to the patient perspective. However, it is important that CMS continuously monitor and refine the questions contained in the HCAHPS survey to avoid any unintended consequences and ensure that the right questions are being asked. For example, research has shown a greater likelihood of low HCAHPS scores reported from patients admitted via the emergency department (ED), as patient-provider interactions often are more limited due to the stressful nature of the ED.[8]

Likewise, there is concern among the health care community of unintended consequences related to changes in physician prescribing practices, in particular, the

[8]Kahn SA, Iannuzzi JC, Stassen NA, Bankey PE, Gestring M. Measuring Satisfaction: Factors That Drive Hospital Consumer Assessment of Healthcare Providers and Systems Survey Responses in a Trauma and Acute Care Surgery Population. *The American Journal of Surgery.* 2015 May;81(5):537-43.

linkage of the pain management dimension questions contained in the HCAHPS surveys to payment incentives in the hospital VBP Program. There is concern that patient satisfaction questions related to pain management might set unrealistic expectations regarding medications for pain relief and may lead to dissatisfaction with care when those expectations are not met. The fact that HCAHPS scores are tied to incentives and reductions in payment for hospitals might create undue pressure for physicians to prescribe opioids to achieve higher patient satisfaction survey results.

We applaud CMS' recognition of the unintended consequences that could arise when the pain management dimension questions in the hospital VBP Program influence opioid prescribing practices, and support the agency's proposal to remove such questions for payment purposes under the hospital VBP Program in FY 2018.

CMS intends that hospitals would continue to use these questions to survey patients about their inpatient pain management experience, but the questions would not affect the level of payment hospitals receive. America's Essential Hospitals supports the collection of such information for purposes of hospital quality improvement efforts. In separating the tie to payment, hospitals and physicians will be able to monitor patient satisfaction and make improvements in pain management care without the potential undue pressure of these performance questions being linked to payment. We encourage CMS to continue to refine the HCAHPS survey, through field testing of alternative pain management questions, with input from stakeholders, as well as its review of all questions contained in the survey to ensure the information collected accurately reflects patient experience in a meaningful way.

6. **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 and do not add administrative burden.**

CMS should continue to tailor the OQR Program measure set to include 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 provide. America's Essential Hospitals supports the creation and use of measures that lead to quality improvement. We encourage CMS to verify that the measures are properly constructed and do not lead to unintended consequences before the agency includes them in the OQR Program.

CMS is not proposing changes to the CY 2018 and 2019 OQR Program measures sets. For CY 2020, CMS proposes to add seven measures: two claims-based and five survey-based. We are particularly concerned with the five survey-based measures derived from the Outpatient Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) survey measures. We ask CMS to consider the following comments before adding new measures to the OQR Program to ensure the measures are reliable, valid, and useful in improving the quality of hospital care and the transparency of public reporting.

a. CMS should await results from the National Quality Forum (NQF) sociodemographic status (SDS) Trial Period before adding the OP-35: Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy measure into the OQR Program.

CMS proposes to add the OP-35 measure beginning with the CY 2020 payment determination. This measure aims to assess the care provided to cancer patients and encourage quality improvement efforts to reduce the number of potentially avoidable inpatient admissions and ED visits among cancer patients receiving chemotherapy in a hospital outpatient setting. The proposed measure was conditionally supported by the Measures Application Partnership (MAP) with the recommendation that the measure be submitted for NQF endorsement with special consideration for SDS adjustments. America's Essential Hospitals urges CMS to include factors related to a patient's background—sociodemographic status, language, and post-discharge support structure—in its risk-adjustment methodology for this measure.

In 2014, NQF convened an expert panel to examine whether the lack of sociodemographic adjustment in performance scores might lead to incorrect conclusions about quality (i.e., the conclusion that hospitals with a disproportionate share of disadvantaged patients provide lower quality care simply as a function of their case mix). The panel, which ultimately recommended risk adjusting certain quality measures for sociodemographic factors, found that excluding such factors could lead to greater disparities in care. For example, disadvantaged populations could lose access to care if providers who work primarily with them are asked to achieve the same results as those who work with wealthier populations.[9] Furthermore, in July 2014, the NQF board of directors approved the SDS Trial Period, which allows inclusion of SDS factors in risk adjustment of performance measure scores when there are conceptual reasons and empirical evidence that inclusion is appropriate.

The results of the NQF SDS Trial Period, along with the Office of the Assistant Secretary for Planning and Evaluation's (ASPE) separate study of risk adjustment for SDS factors in quality measures, are forthcoming. We urge CMS to adjust for these factors in the interim, as a growing body of independent literature demonstrates the significant impact these factors have vulnerable populations and supports risk adjustment.[10] Alternatively, **we ask that CMS delay adoption of the OP-35 measure until the NQF and ASPE findings are thoroughly reviewed.**

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[9]See, e.g., NQF Technical Report. *Risk Adjustment for Socioeconomic Status or Other Sociodemographic Factors*. August 2014. http://www.qualityforum.org/Publications/2014/08/Risk_Adjustment_for_Socioeconomic_Status_or_Other_Sociodemographic_Factors.aspx. Accessed June 2015.

[10]See, *e.g.*, America's Essential Hospitals. Sociodemographic Factors Affect Health Outcomes. October 21, 2015. http://essentialhospitals.org/institute/sociodemographic-factors-and-socioeconomic-status-ses-affect-health-outcomes/. Accessed June 2016.

b. CMS should delay adoption of the OP-37a-e: Outpatient Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) survey measures by the OQR Program.

CMS proposes to adopt five survey-based measures derived from the OAS CAHPS Survey for the CY 2020 payment determination and subsequent years. The OAS CAHPS survey collects information about patients' experiences of care in hospital outpatient departments and ambulatory surgery centers. The survey was initially implemented as a voluntary national reporting program in January 2016, with the first publicly reported data to be posted in 2018. The survey covers topics such as access to care, communications, and experience at a facility.

The five measures proposed for adoption into the OQR Program consist of three composite measures—About Facilities and Staff; Communication About Procedure; and Preparation for Discharge and Recovery—as well as two global measures, each composed of a single question that asks the patient to rate the overall care the hospital provided and their recommendation of the facility. Under the proposed rule, hospitals would be required to begin collecting data for these measures on January 1, 2018. America's Essential Hospitals supports efforts to better understand patients' experiences in the outpatient setting. However, **we urge CMS to continue development of the OAS CAHPS survey and delay adoption until appropriate adjustments are made to lower the administrative burden of the survey.**

There are three approved modes of administration: mail only, telephone only, and mail with a telephone follow-up. CMS does not propose the use of information technology in survey administration of the OAS CAHPS survey. Lack of use of information technology is a hindrance and increases burden unnecessarily. Additionally, CMS would require the use of a CMS-approved survey vendor, which will be an additional and undue financial burden on essential hospitals, which already face limited resources. CMS should provide flexibility in the administration of this survey.

Further, we urge CMS to consider factors that influence survey administration and that might create undue hardships for essential hospitals, including additional resources needed to effectively communicate with people who have limited English proficiency (LEP). While people with LEP account for about 8 percent of the U.S. population overall, they represent more than 20 percent of the uninsured population and 12 percent of the Medicaid population.[11] Language barriers jeopardize the health of many LEP individuals, and their communities, by affecting their ability to access care and communicate with providers. Members of America's Essential Hospitals work daily to engage patients in their care and break down language barriers that might keep patients from accessing high-quality health care and preventative services. However, care management for this population requires time and resources to ensure that follow-up is provided—and provided in a culturally sensitive manner that recognizes and respects the needs and preferences of each patient.

[11] Gonzales, G. 2014. "State Estimates of Limited English Proficiency by Health Insurance Status." Issue Brief #40. Minneapolis, MN: State Health Access Data Assistance Center, University of Minnesota.

A growing body of evidence demonstrates that language concordance between patients and caregivers increases patient satisfaction, patient-reported health status, and adherence with medication and follow-up visits.[12] Vulnerable populations treated by essential hospitals might have difficulty completing surveys due to language barriers and low health literacy, and will require additional support and outreach from facilities administering the survey to these populations. **We urge CMS to closely examine the necessity and utility of the proposed OAS CAHPS measures and adjust for all factors that could influence how patients respond to the survey but are beyond the control of the hospital and not directly related to hospital performance.**

Last, **CMS should only adopt measures in the OQR Program that are NQF-endorsed and should continuously monitor the measures in the program and proposed new measures for NQF endorsement status.** The proposed OAS CAHPS survey-based measures are not currently NQF-endorsed. NQF endorsement and approval by the MAP are imperative to ensure measure validity and reliability. Through these processes, measures are fully vetted and approved through a consensus-building approach that involves the public and interested stakeholders. CMS does note that the proposed OAS CAHPS survey measures were initially included in the measures under consideration (MUC) list and reviewed by the MAP. However, it is important to recognize that the MAP encouraged continued development of these measures and the current measures have not been resubmitted for MAP review. CMS should not add measures that have not yet been fully through the vetting processes.

For the above stated reasons, we urge CMS to delay inclusion of the OP-37a-e measure beyond the proposed January 1, 2018, implementation date, due to the need for further measure development.

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

For CY 2017, 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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[12]Manson A. Language Concordance as a Determinant of Patient Compliance and Emergency Room Use in Patients with Asthma. *Med Care.* 1988;26(12):1119–28.

America's Essential Hospitals appreciates the opportunity to submit these comments. If you have questions, please contact Erin O'Malley, director of policy, at 202-585-0127.