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September 6, 2016

Andrew M. Slavitt  
Acting Administrator  
Centers for Medicare & Medicaid Services  
Hubert H. Humphrey Building  
200 Independence Avenue, S.W., Room 445-G  
Washington, DC 20201

***RE: CMS-1656-P, Medicare Program; Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Payment to Certain Off-campus Outpatient Departments of a Provider; Proposed Rule (Vol. 81, No. 135), July 14, 2016.***

Dear Mr. Slavitt:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our 43,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) calendar year (CY) 2017 hospital outpatient prospective payment system (OPPS) proposed rule. Our comments address the proposals that would implement the hospital outpatient department (HOPD) site-neutral provisions contained in Section 603 of the Bipartisan Budget Act of 2015 (BiBA). We also comment on other provisions within the proposed rule, including changes to packaging policies, the comprehensive ambulatory payment classifications (C-APCs), the inpatient-only list, the Outpatient Quality Reporting (OQR) Program and Electronic Health Record (EHR) Incentive Program.

**The AHA is extremely concerned about CMS's implementation of the BiBA site-neutral provisions, which would prevent hospitals from being able to continue to provide the current level of necessary, innovative and high-quality health care in their communities. The hospital field and more than half of the U.S. House and Senate this spring urged CMS to provide reasonable flexibility when implementing the BiBA site-neutral provisions in order to ensure that Medicare patients have continued access to the highest quality hospital outpatient care in their communities. Instead, CMS has proposed a short-sighted and unworkable set of policies that provide no reimbursement directly to hospitals in CY 2017 for the services they provide to Medicare beneficiaries. It is irresponsible for CMS to move forward with these site-neutral policies until it can adopt much-needed changes. CMS must delay its policies until it can provide fair and equitable payment to hospitals for the services they provide.**



Site-neutral Proposal for 2017. CMS proposes to make *no payment* to newer “nonexcepted” off-campus HOPDs for the services they provide to Medicare beneficiaries in 2017. In other words, the agency would not provide any reimbursement to HOPDs for the nursing, laboratory, imaging, chemotherapy, surgical and many other reasonable and necessary services they provide to Medicare beneficiaries. **Such a payment policy is completely unjustified.** Specifically, while it may not be simple, CMS clearly has a mechanism at its disposal that it could use to pay hospitals directly for nonexcepted services under the Medicare physician fee schedule (PFS). **The agency has a responsibility to work to be able to use this, or another, mechanism to provide reasonable payment to hospitals, and it must delay implementation of its site-neutral policies until it does so.** Indeed, CMS made such types of delays in the past when it was unable to implement payment systems in a timely and responsible manner. For instance, CMS delayed the implementation of the OPFS for 18 months, the ambulance fee schedule for 27 months and the new market-based payment system for the clinical laboratory fee schedule for 12 months.

Additionally, as we detailed in our [Aug. 26, 2016 letter](#), **we are concerned that CMS’s proposed payment policy could put hospitals at risk of running afoul of federal fraud and abuse laws.** This concern exists whether hospitals are able re-negotiate contracts with the physicians that provide services in their nonexcepted HOPDs or leave the existing contracts intact because CMS’s policy provides physicians with additional funds in the form of payment for HOPD services for which they previously paid nothing.

A delay also would provide CMS with the time it needs to operationalize other policies necessary to properly implement these site-neutral regulations and to address the many complex billing, cost-reporting and payment policy questions that arise as a result of the agency’s proposal to identify the PFS as the applicable payment system for nonexcepted items and services.

Site-neutral Proposal for 2018 and Beyond. As CMS considers how to establish a more reasonable and workable payment policy for 2018 and beyond, the AHA urges the agency to further examine its other proposals related to site-neutrality, as outlined below. We are concerned that, as written, the rule would freeze the progress of off-campus clinical care in its tracks and would negatively impact access to care for Medicare beneficiaries. In particular, the agency’s proposal to limit flexibility in relocation, expansion and change of ownership, in combination with its proposal to withhold hospital payments altogether, would mean that hospitals and health systems that have planned to provide or expand much-needed hospital-level outpatient care in urban and rural communities with limited access to care would not be able to do so. Given the rapid pace of technological advances in medicine, the treatments and services offered by HOPDs today will inevitably evolve into newer, innovative and more effective care in the future. CMS’s policy should not hamper patient access to innovative technologies and services.

**We recommend that CMS:**

- **allow excepted HOPDs to relocate and rebuild without triggering payment cuts;**

- **protect hospitals' ability to offer expanded lines of services without experiencing a loss of reimbursement; and**
- **allow the ownership of individual HOPDs to be transferred from one hospital to another and maintain their excepted status.**

Additional Recommendations. The AHA also makes the following recommendations regarding other payment proposals included in the rule, including:

- The AHA opposes the removal of total knee arthroplasty from the inpatient only list. We do not believe it is clinically appropriate, and are further concerned that it could put the success of the Comprehensive Care for Joint Replacement and the Bundled Payment for Care Improvement initiative programs at risk.
- The AHA supports CMS's proposal to finalize the 90-day EHR reporting period for 2016 and reduced thresholds for some Modified Stage 2 and Stage 3 requirements. We also urge CMS to finalize a Stage 3 start date no sooner than 2019 and refrain from unrealistic Stage 3 requirements, such as the required use of application program interfaces.
- The AHA believes the implementation of the Outpatient and Ambulatory Surgery Center Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) survey is premature. We urge CMS to minimize duplication between OAS CAHPS and other surveys in the CAHPS family, and to develop guidelines for and allow the use of more economical survey administration modes, such as email and web-based surveys.
- The AHA supports CMS's proposal to exclude the results from three pain-management questions in the Hospital CAHPS survey in determining hospitals' Value-based Purchasing Program scores.

Our detailed comments on the proposed rule are attached. If your team has any questions or would like to discuss further, Roslyne Schulman, director of policy, is the point of contact at the AHA. You can reach her at (202) 626-2273 or [rschulman@aha.org](mailto:rschulman@aha.org).

Sincerely,

/s/

Thomas P. Nickels  
Executive Vice President

*Attachments*

**American Hospital Association (AHA)  
Detailed Comments on the Outpatient Prospective Payment System (OPPS)  
Proposed Rule for Calendar Year (FY) 2017**

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## **PROPOSED IMPLEMENTATION OF BIBA SITE-NEUTRAL PAYMENT PROVISIONS IN CERTAIN OFF-CAMPUS PROVIDER-BASED HOPDS**

Section 603 of the Bipartisan Budget Act (BiBA) of 2015 enacted site-neutral payment reductions for Medicare services that are furnished in newer off-campus provider-based hospital outpatient departments (HOPDs) that are not dedicated emergency departments (EDs). A “new” HOPD is defined as an off-campus provider-based department of a hospital that first furnished and billed for Medicare hospital outpatient services on or after the date of BiBA’s enactment (Nov. 2, 2015), but is not a dedicated ED. The Centers for Medicare & Medicaid Services (CMS) refers to these HOPDs, as well as the items and services they furnish, as “nonexcepted.” BiBA states that such nonexcepted HOPDs would not be eligible for outpatient prospective payment system (OPPS) reimbursements beginning Jan. 1, 2017, and instead would be paid under another applicable Part B payment system.

The hospital field and more than half of the U.S. House and Senate this spring urged CMS to provide reasonable flexibility when implementing the BiBA site-neutral provisions in order to ensure that Medicare patients have continued access to the highest quality hospital care in their communities. Instead, CMS has proposed a short-sighted and unworkable set of policies that provide no reimbursement to hospitals in 2017 for the nonexcepted items and services they furnish to Medicare beneficiaries. The agency’s proposals would prevent hospitals from being able to provide necessary, innovative and high-quality health care to their communities and cannot be reasonably implemented. **CMS must delay these site-neutral policies until it can adopt much-needed changes (as described below) in order to provide fair and equitable payment to hospitals for the services they provide.**

## **PROPOSED CY 2017 PAYMENT POLICY FOR NONEXCEPTED HOPDS**

For CY 2017, CMS proposes that the Medicare physician fee schedule (PFS) would be the “applicable payment system” for the majority of nonexcepted items and services furnished in an off-campus HOPD. *Under this proposal, there would be no payment made to the hospital by Medicare.* Instead, physicians furnishing such services would bill on the professional claim (CMS 1500/837P) and be paid at the higher “nonfacility” rate under the PFS for the services for which they may bill. In other words, the agency would not provide any reimbursement to nonexcepted HOPDs for the nursing, laboratory, imaging, chemotherapy, surgical and many other reasonable and necessary services they provide to Medicare beneficiaries.

**Such a payment policy is completely unjustified.** Many of the nation’s hospitals and health systems are in the process of redesigning delivery systems to increase value and better serve patients by improving the patient experience of care, improving the health of populations and reducing the per capita cost of health care. This involves bringing much needed hospital-level care closer to the patients who require such services. **However, the policies CMS proposes in order to implement the site-neutral provisions of BiBA would not only prevent hospitals and health systems from achieving these critical goals, but also could result in their not**

**being able to continue to provide necessary, innovative and high-quality health care in their communities.**

**While it may not be simple, CMS clearly has a mechanism at its disposal that it could use to pay hospitals directly for nonexcepted services under the PFS.** CMS claims that it cannot pay hospitals directly under a non-OPPS Medicare Part B payment system in 2017 because, “at a minimum, numerous complex systems changes would need to be made to allow an off-campus provider-based department to bill and be paid as another provider or supplier type.” However, CMS currently pays hospitals, through the institutional claim (Uniform Bill (UB04)/837I), at the Medicare PFS rate for a wide variety of services and situations, including screening and diagnostic mammography, physical therapy and other types of therapy services, and certain preventive services. It also reimburses hospitals via the Critical Access Hospital (CAH) Optional Payment Method (Method II) at PFS rates using the institutional claim. **The agency has a responsibility to use the current institutional claim or another mechanism to provide reasonable payment to hospitals. CMS must not implement its site-neutral policies until it can find a way to appropriately pay hospitals for the items and services they provide in the care of patients.**

Additionally, as we detailed in our [Aug. 26, 2016 letter](#), **we are concerned that CMS’s proposed payment policy could put hospitals at risk of running afoul of federal fraud and abuse laws.** This concern exists whether hospitals are able re-negotiate contracts with the physicians that provide services in their nonexcepted HOPDs or leave the contracts intact because CMS’s policy provides physicians with additional funds in the form of payment for HOPD services for which they previously paid nothing.

Indeed, CMS made such types of delays in the past when it was unable to implement payment systems in a timely and responsible manner. These include the:

- *OPPS.* CMS delayed the implementation of the OPPS for 18 months, from Jan. 1, 1999 to July 1, 2000 due to the need to make Year 2000 (Y2K) systems changes. In the Sept. 8, 1998 proposed rule CMS stated: “Implementation of outpatient PPS is one of the projects that must be delayed by the year 2000 system renovations, because it requires massive system changes...It would be irresponsible to continue activity that would create a real danger that basic enrollment and claims processing activities will be disrupted, with far worse consequences for providers and beneficiaries than delay in implementation of outpatient PPS will cause.”
- *Ambulance Fee Schedule.* CMS delayed the ambulance fee schedule for 27 months, from Jan. 1, 2000 to April 1, 2002. In the Feb. 27, 2002 final rule, CMS stated: “Section 4513(b)(3) of the BBA, which added section 1834(1)(3) to the Act, provided that the fee schedule was to be effective for ambulance services furnished on or after January 1, 2000. However, because of other statutory obligations, the scope of systems changes required to implement the ambulance fee schedule, and the need to ensure that our computerized systems were compliant with the Year 2000 (Y2K) requirements, we could

not meet this statutory deadline. In the September 12, 2000 proposed rule, we indicated our intention to implement the fee schedule beginning January 1, 2001. However, although the proposed rule was largely based on an agreement reached as part of a negotiated rulemaking process with representatives of the ambulance industry and other interests, we received over 340 public comments. We did not have sufficient time to carefully consider all comments and publish a final rule in time to implement the fee schedule by January 1, 2001. This final rule establishes an implementation date of April 1, 2002.”

- *Market-based Payment System for the Clinical Laboratory Fee Schedule (CLFS)*. Most recently, CMS delayed the new CLFS for 12 months, from Jan. 1, 2017 to Jan. 1, 2018. In the June 23, 2016 final rule, the agency stated: “We recognize that entities will need sufficient time after the publication of the final rule to build the information systems necessary to collect private payor rates, and review and verify the data collected to ensure their accuracy. We understand that moving the implementation date to January 1, 2018 would allow for those activities as well as independent validation testing of our system to which reporting entities will report applicable information and could also provide laboratories time to perform end user testing prior to the data reporting period. A January 1, 2018 implementation date would also allow laboratories to complete the registration processes for submitting applicable information well ahead of the data reporting period. We also appreciate that stakeholders are particularly concerned about having sufficient time to prepare for the new CLFS in light of the potential for civil monetary penalties. For all of these reasons, we agree with the commenters that we should move the implementation date of the new CLFS.”

CMS’s Proposed Payment Options for CY 2017 are Unacceptable. CMS’s proposed rule gives hospitals two options with regard to receiving any payment at all for OPSS services provided in nonexcepted off-campus HOPDs in 2017:

1. Option 1: The proposed rule would have Medicare make payment for any PFS services at the nonfacility rate *to the physician or practitioner*.
2. Option 2: The non-expected off-campus HOPD could enroll in Medicare as another provider/supplier type.

**Neither of these payment options are acceptable.** Regarding Option 1, Medicare’s PFS payment is higher in the nonfacility setting and lower in the facility setting so as to recognize that when a physician/practitioner furnishes a service in the office, the physician/practitioner incurs the cost of the clinical staff, equipment and supplies. In the facility setting, the physician/practitioner does not incur these direct costs and Medicare makes a lower payment. In this circumstance, Medicare also makes payment to the hospital for its direct costs *and its institutional indirect costs* that are associated with the providing services in a HOPD.

However, under this option, not only does CMS not provide payment for the hospital’s costs associated with providing a service, but it also would pay the physician for the hospital’s direct costs – costs that the physician does not actually incur. CMS expects hospitals to then obtain

reimbursement from the physician. This raises a multitude of issues for hospitals with adherence to fraud and abuse laws (reassignment, anti-markup, self-referral and anti-kickback). In the AHA's [Aug. 26 letter](#) to CMS, which contains a legal analysis from Hogan Lovells, we state our belief that this proposed policy is infeasible to implement *at all*, much less by Jan. 1, 2017.

Option 2 would require a nonexcepted off-campus HOPD to give up its status as a hospital in order to receive payment from Medicare for reasonable and necessary services. **We believe this option is counter to the statutory provision in that BiBA does not change a nonexcepted HOPD's status as a hospital.** BiBA merely indicates that the site can no longer be paid under the OPDS. We do not believe it is reasonable for CMS to require a nonexcepted off-campus HOPD to give up its status as part of the hospital in order to receive payment from Medicare for services provided when the law itself is clear that the site maintains its status as part of the hospital. The law's only prohibition is on these sites being paid under the OPDS.

**As stated previously, CMS has a responsibility to provide reasonable payment to hospitals and cannot implement its site-neutral policies until it does so.**

Data Collection. **A delay also would provide CMS with the time it so clearly needs to operationalize other policies necessary to properly implement these site-neutral regulations.** For example, in the proposed rule, CMS acknowledges that it does not currently have a way to determine the status of individual HOPDs as excepted or nonexcepted. Nor does the agency have a way to determine which lines of service individual HOPDs offered prior to Nov. 2, 2015. Without such information, the agency cannot ensure that its CY 2017 payment policy would be implemented correctly and enforced fairly. Even if CMS required additional data collection, the two months between the release of the final rule (expected around Nov. 1) and the proposed implementation date of Jan. 1, 2017 would not provide sufficient time for either the agency to develop and test a system to gather this information from hospitals, or for hospitals to accurately and reliably report this data. Clearly, CMS needs additional time to develop and carry-out an accurate and reliable data collection that will inform the correct implementation of BiBA's site-neutral provisions.

Many Gaps In Billing and Payment Policy Remain for CY 2017. In addition to being unreasonable and unsustainable, CMS's proposed policy for CY 2017 leaves important billing, cost-reporting and payment policy questions unanswered. For instance, because nonexcepted HOPDs would still be provider-based departments, hospitals would need to track their costs and charges for cost-reporting purposes and for certain important programs, such as the 340B Drug Pricing Program. **We urge CMS to provide guidance on how hospitals would record these costs and charges on the cost report as soon as possible.**

In addition, there are many gaps regarding whether and how certain types of physician services would be paid in nonexcepted HOPDs under the current PFS rules because there are many services provided in HOPDs where payment is not available under the PFS. There are still other circumstances where payment under the PFS is applicable but the Medicare statute and/or its rules and regulations preclude the payment that CMS is proposing to make. For instance:



- Outpatient hospital services rendered “incident-to” physicians’ services (as described in Section 1861(s)(2)(B) of the Social Security Act), such as chemotherapy infusions, are only priced in nonfacility (office-based) settings under the PFS. They are not covered by the PFS when they are furnished in a HOPD setting because the physician does not incur the cost of the services. Instead they are paid under the OPSS. Further, making payment to the physician for “incident to” services furnished in a nonexcepted HOPD is counter to CMS’s “incident to” regulations at 42 CFR § 410.26 (b)(1) which state “services and supplies must be furnished in a non-institutional setting to non-institutional patients.” In a similar manner, we believe the agency’s manual Publication 100-01, Chapter 15, section 60.1 raises a further problem with CMS’s proposal, as it states that services and supplies billed under the “incident to” provision “must represent an expense to the physician or legal entity bill [for the] services or suppliers.” Thus, it is unclear what, if any, payment would be furnished for the provision of “incident-to” services, such as chemotherapy infusion, as payment would not go to the physician or the HOPD.
- Diagnostic services, in particular, the technical component (TC) of diagnostic services, such as chest X-rays, when furnished in HOPDs (as described in Section 1861(s)(2)(C)) have no facility relative value units (RVUs). Similar to “incident-to” services, this is because the physicians do not incur the cost for the services. Currently, such TC services are only paid under the OPSS when furnished in a facility setting.
- It appears that Part B drugs furnished in nonexcepted HOPDs could not be paid under the PFS since Part B drugs are considered to be incident-to services in Section 1861(s)(2)(B) of the Social Security Act and, like other incident-to services, the physician does not incur the cost for Part B drugs furnished in a HOPD. Therefore, would nonexcepted HOPDs be able to continue to bill for Part B drugs under the OPSS? If so, how would the OPSS drug packaging threshold or the policy-packaged drug policies apply to nonexcepted HOPDs? Since the OPSS methodology would no longer apply to nonexcepted HOPDs, would Medicare pay hospitals for all Part B drugs separately using the average sales price methodology under Section 1847A? How would Part B drugs be paid when they are furnished in an excepted HOPD but the encounter includes both excepted and nonexcepted services?
- Payment for clinical diagnostic laboratory services furnished in nonexcepted HOPDs are not clearly addressed in the rule. Specifically, the rule does not clearly indicate whether such services would be paid separately under the CLFS on an institutional bill or whether the OPSS rules for packaging of laboratory tests would continue to apply in nonexcepted provider-based HOPDs. Further, it is unclear how laboratory services would be paid in excepted HOPDs where a mix of excepted and nonexcepted services are furnished in conjunction with laboratory tests during the same patient encounter.
- Under Section 1833(t)(1)(B)(iv) of the Social Security Act, therapy services (such as physical therapy, occupational therapy and speech-language therapy), screening and diagnostic mammography and certain preventive services are not covered outpatient

department services when furnished in an HOPD, and instead are billed on an institutional bill and paid at the PFS rates. Would these services continue to be covered and paid in this manner in CY 2017? If an excepted HOPD furnishing such services relocates on or after Nov. 2, 2015 or if it expands and begins furnishing these services on or after Nov. 2, 2015, would these services continue to be able to be billed and paid as they are currently?

- Observation services and partial hospitalization program (PHP) services are not currently payable under the PFS and it is unclear how they would be paid when furnished in nonexcepted HOPDs.
- Services that do not have nonfacility RVUs, such as certain surgeries, are only priced in facility (HOPD) settings because they are rarely, if ever, furnished outside of the hospital. CMS proposes to pay physicians in CY 2017 at the nonfacility rate for services furnished in nonexcepted HOPDs, but these services have no nonfacility RVUs. We understand that currently, Medicare will pay for services that are not priced in nonfacility settings at the facility rate when it receives a claim for such service with a nonfacility place of service. CMS does not specifically state whether it is planning to use this approach for nonexcepted HOPDs, but if it is, we stress that this facility payment amount would be insufficient as it does not include compensation for any direct costs such as clinical staff, medical supplies and medical equipment that are explicitly recognized when CMS determines payment at the nonfacility rate.

**Without answers to these questions, hospitals that have made substantial investments in new off-campus HOPDs or those that have been planning to relocate or expand existing off-campus HOPDs are facing untenable financial risk in moving forward with these plans.**

These uncertainties also would harm beneficiary access to care if hospitals find that the financial risks are too great and they cannot move forward with plans to bring hospital-level outpatient care closer to otherwise underserved rural and urban communities.

**Even if CMS answers these questions, the two-month-period between the publication of the final rule and the Jan. 1, 2017 effective date is not nearly enough time for hospitals and physicians to use such information to negotiate or re-negotiate arrangements that ensure fair payment for the use of the hospital personnel, facilities, equipment and supplies.** As detailed in our [Aug. 26, 2016 letter](#) regarding the interaction between CMS's proposal and the federal fraud and abuse laws, we are concerned that hospitals that need to re-negotiate contracts could run afoul of those laws.

The Impact of Other Laws and Regulations on CMS's Proposed Payment Policy for 2017. CMS states that its proposal to pay under the PFS for all nonexcepted items and services "may result in hospitals establishing business arrangements with the physicians or nonphysician practitioners who bill under the MPFS." CMS seeks public comment on the impact of a number of laws and regulations on their proposed policy. The AHA refers CMS to its of [Aug. 26, 2016 letter](#) in which the interaction between the federal fraud and abuse laws and CMS's proposed payment

policy are discussed, as well as **our concerns that CMS's proposed payment policy could put hospitals at risk of running afoul of federal fraud and abuse laws. This is yet another reason that the only workable approach is for CMS to delay implementation of the site-neutral provisions of BiBA in order to allow adequate time for the agency, in consultation with the provider community, to create a fair, reasonable and legally sound payment system for nonexcepted items and services in off-campus HOPDs.**

## **CONSIDERATIONS FOR CY 2018 AND BEYOND**

As CMS considers how to establish a more reasonable and workable payment policy for 2018 and beyond, the AHA urges the agency to further examine its other proposals related to site-neutrality, as outlined below. **As written, we are deeply concerned that the proposed policies would freeze off-campus clinical care in its tracks, negatively impacting access to care for beneficiaries.** For example, the agency's proposal to limit flexibility in relocation/rebuilding, expansion and change of ownership, in combination with its proposal to withhold hospital payments altogether, would mean that hospitals and health systems that have planned to provide or expand much-needed hospital-level outpatient care in urban and rural communities with limited access to care would not be able to do so.

**We firmly believe that Congress did not intend that the site-neutral provisions of BiBA be implemented so inflexibly.** In fact, the plain language of Section 603 does not mention relocation, expansion or change of ownership. Had Congress intended to prohibit the relocation, expansion or change of ownership of excepted HOPDs, it could easily have included that in Section 603; however, it did not. Instead, in the proposed rule, CMS makes policy choices based primarily on its belief that they reflect congressional intent. However, as noted above, with more than half of the House and the Senate requesting that CMS provide reasonable flexibility when implementing Section 603, clearly CMS misunderstands what Congress intended.

**Relocation and Rebuilding. The AHA is particularly troubled by CMS's unreasonable and inflexible proposal to discontinue current reimbursement under the OPPS for excepted HOPDs that relocate or rebuild on or after the date of enactment.** Specifically, CMS proposes that an excepted off-campus HOPD must maintain the same physical address that was listed on the provider's hospital Medicare enrollment form (including the unit or suite number for an off-campus HOPD located in a multi-office building), as of Nov. 1, 2015 in order to maintain its excepted status and continue to be paid at the OPPS rates. An excepted off-campus provider-based HOPD that changes its location, even if only the suite number, would lose that status and be subject to the site-neutral payment policy as of Jan. 1, 2017.

**CMS should allow for relocation and rebuilding of excepted HOPDs without triggering payment cuts.** There are many necessary and valid reasons that excepted HOPDs would need to relocate, such as:

- being located on an earthquake fault line and needing to come up to building codes;
- being located on a revised flood plain and needing to come up to building codes;

- having a lease expire;
- becoming damaged or obsolete; or
- becoming too small because of population shifts and increased patient volumes.

Relocation under such circumstances should not cause these excepted HOPDs to lose OPSS payment. The impact on patients, including the loss of access to needed care, would be drastic in the communities served by these off-campus HOPDs. Furthermore, CMS's proposed policy on relocation exposes hospitals to another potential harm. Landlords who hold the leases of excepted HOPDs may demand otherwise unwarranted rent increases when the leases have to be renewed, essentially holding the hospital hostage to either pay up or potentially move and lose their OPSS payments.

For example, one of our large rural health system members has hospitals that frequently serve as the sole provider of health care in their communities. The health system's off-campus HOPDs offer hospital-level services in their communities, improving access to care in rural areas that are underserved by physician clinics and with populations that tend to be poorer, older and sicker. One of this system's hospitals has an obsolete off-campus HOPD that suffers from frequent flooding and sinkholes. This HOPD also has a lease that soon will be ending, and the facility has determined that it could better serve its community by moving to a new location on higher ground. However, the health system is concerned that by relocating, the HOPD would lose its excepted status.

**Since Section 603 of BiBA does not actually discuss or address relocation, the AHA believes that CMS has the authority to allow more flexibility in its interpretation than it has, so that off-campus HOPDs are not frozen at the point in time at which when the law was enacted. In fact, CMS has allowed such flexibility in similar situations in the past.** For example, the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 eliminated the ability for states to designate necessary provider CAHs. When doing that, Congress indicated that existing necessary provider CAHs would continue to be considered as such. In addition, similar to BiBA, the MMA was silent regarding how relocation and renovation of necessary provider CAHs should be handled. However, CMS implemented regulations that provided reasonable flexibility, allowing grandfathered CAHs to relocate and rebuild so long as they met specific requirements that ensured they remained essentially the same provider and continued to provide services to the same rural service area. **The AHA recommends that CMS apply similar flexibility in order to allow excepted off-campus HOPDs to relocate or rebuild.**

At the very least, the AHA urges CMS to follow-through on its intention to create clearly defined relocation exceptions. **We recommend that excepted HOPDs, both on-campus and off-campus, be permitted to relocate without the loss of excepted status in any and all of the following circumstances:**

- *Relocation to comply with federal/state requirements.* This would include, for example, HOPDs that need to relocate due to state seismic rules, a change in a flood plain or any other determination that the location or the structure of the HOPD is unsafe and must be relocated.

- *The relocation of an HOPD that has been destroyed or substantially damaged in a disaster or emergency.* This would include circumstances such as a facility that has been damaged by a fire, flood, hurricane or tornado.
- *The temporary relocation of an HOPD in order to allow rebuilding, updating or retrofitting of its infrastructure.* This would include circumstances such as the need to make repairs to a damaged facility or to make improvements to an obsolete facility in order to bring it up to code.
- *Relocation due to the HOPD losing its lease.*
- *Relocating an HOPD in order to provide access to care in an underserved area.*
- *Relocation due to a shifting/growing patient population.*

Furthermore, in order to avoid imposing unnecessary delays and burdens on providers who must relocate due to such circumstances, the AHA recommends that the process to obtain an exception be simple, timely and, ideally, not require a formal approval process. Instead, a hospital or health system should be able to notify CMS in a predetermined way that its relocation meets one of the exceptions that CMS has approved in advance. One approach that holds promise would be to use the existing Medicare provider enrollment process. For instance, when a hospital updates its enrollment information to inform CMS of a change in practice location, there could be a new section added to the Medicare 855 enrollment form and the online Medicare Provider Enrollment, Chain, and Ownership System (PECOS) that the hospital would use to notify CMS of the reason for a relocation of an excepted HOPD by choosing among the list of pre-approved exceptions. **In addition, CMS's regional offices should have discretionary authority to approve additional relocation exceptions for off-campus HOPDs in other reasonable, but unforeseen, circumstances.**

Expansion of Services. CMS proposes that, if an excepted HOPD expands the lines of service it offers on or after Nov. 2, 2015, those new services would be paid at the site-neutral rate. **This proposal is extremely problematic.** Off-campus HOPDs must be able to expand the items and services that they offer in order to meet changes in clinical practice and the changing needs of their communities without losing their ability to be reimbursed under the OPSS. Given the rapid pace of technological advances in medicine, the treatments and services offered by HOPDs today will inevitably evolve into newer, innovative and more effective care in the future. **CMS's policy must not hamper access to innovative technologies and services.**

For example, a member health system in New Jersey has plans to expand the services it offers in an excepted HOPD. In an effort to provide comprehensive cancer care services to patients in one convenient location, it plans to add chemotherapy infusion services to an existing off-campus HOPD that currently has an imaging center, clinical laboratory, physician offices and a vascular procedure center. However, the prospect of losing OPSS payments in an expansion reduces the

likelihood that such an expansion will take place, to the detriment of meeting community needs. We have heard from many hospitals and health systems who are in similar predicaments; having planned expansions of service in order to offer patients greater access to high-quality, fully integrated care in locations that are closer to growing populations, but which must now rethink their plans due to CMS's restrictive policy on expansion of services.

**Nothing in BiBA requires that CMS treat expanded services in an excepted HOPD in this way. CMS should ensure that patients continue to have access to the services they need at the facilities where they seek treatment by protecting hospitals' and health systems' ability to offer an expanded range of services without experiencing a loss of reimbursement.**

*Definition of "Department of a Provider."* **There is a reasonable argument to be made that BiBA's reference to "a department of a provider (as defined in section 413.65(a)(2) of title 42 of the Code of Federal Regulations, as in effect as of the date of the enactment of this paragraph)" indicates that Congress intended to allow expansion of services at excepted HOPDs.** That is, in defining which off-campus HOPDs are excepted from the site-neutral payment, BiBA specifically references the provider-based regulation's definition of a "department of a provider" as it existed at enactment. This means that CMS must consider the *entire regulatory definition* in developing its policies. However, in the proposed rule, CMS considers only *select phrases*, focusing on only one part of this regulatory definition in justifying its policies to not allow excepted status to continue when a provider-based HOPD relocates or expands. That is, the agency cites only the part of the definition that states: "A department of a provider comprises both the specific physical facility that serves as the site of services of a type for which payment could be claimed under the Medicare or Medicaid program, and the personnel and equipment needed to deliver the services at that facility."

However, the first part of the regulatory definition, which also must be considered under the law, states that the "Department of a provider means a facility or organization that is either created by, or acquired by, a main provider *for the purpose of furnishing health care services of the same type as those furnished by the main provider* under the name, ownership, and financial and administrative control of the main provider, in accordance with the provisions of this section." We believe that this means that expansions in services at an excepted off-campus HOPD may occur because they are furnishing services "of the same type as those furnished by the main provider." **Therefore, we believe that Congress intended to except provider-based off-campus HOPDs that were furnishing services under the hospital's provider number prior to Nov. 2, 2015, including all current and future services provided at that HOPD's location because, by definition, they are "of the same type as those furnished by the main provider."** In other words, unlike free-standing physician practices, provider-based HOPDs are, by definition, fully integrated with their main hospital. This includes complying with the same Medicare conditions of participation and conditions of payment and full integration of their clinical, financial and administrative functions. This is consistent with how many HOPDs operate and, indeed, with the other parts of the provider-based regulations at 42 CFR 413.65, which are designed to ensure integration with the main hospital. Services change over time at the main provider and similarly at the on-campus and off-campus HOPDs as the practice of medicine evolves and the needs of patients change.

***Issues Regarding the Use of Clinical Families.* CMS's proposed policy for handling expansion of services in excepted HOPDs introduces substantial complexity into an already overly complex payment system and, further, continues to raise operational issues that are not addressed in the proposed rule.** That is, the agency proposes that any expansion of services beyond the clinical families of services that had been furnished by an excepted HOPD prior to Nov. 2, 2015 would be paid according to the site-neutral payment policy. Service types would be defined by 19 clinical families of hospital outpatient services, composed of groups of ambulatory payment classifications (APCs), as listed in the proposed rule. As such, the agency proposes that if an excepted off-campus HOPD furnishes any specific service within a new clinical family of services that it had not furnished and billed for before Nov. 2, 2015, that service would be nonexcepted and ineligible to receive payment under the OPSS.

We have several concerns. First, the use of APCs to define clinical families raises questions related to how CMS would manage this issue as APCs are redefined and maintained over time. Each year, CMS changes the composition and definition of APCs and the Current Procedural Terminology (CPT)/Healthcare Common Procedure Coding System (HCPCS) codes contained in those APCs. Therefore, the individual services contained within a clinical family, as defined by the groupings of APCs described in the proposed rule for 2017 would change. How would CMS and providers track such changes? How would CMS treat changes in the component HCPCS/CPT codes and in the APCs themselves as it relates to items and services offered in excepted HOPDs?

Furthermore, the AHA notes that there are several categories of OPSS-covered HCPCS/CPT codes that CMS has neglected to assign a clinical family. These include drugs, new technology APCs, partial hospitalization, various emergency services (e.g., resuscitation and cardioversion, ventilation initiation and management, ancillary outpatient services when a patient dies) and dialysis. It is unclear whether this is an oversight or error in the proposed rule or if the agency has some other unstated intention regarding these services. For instance, does the lack of a clinical family assignment mean that the prohibition on the expansion of services concept does not apply to these APCs and that any of these services can be provided at an excepted off-campus HOPDs on or after Nov. 2, 2015 without triggering site-neutral payment? Since new technology APCs are not listed among the proposed families of service, what happens when CMS reassigns a CPT code currently contained within a new technology APC to a new or existing APC within a listed clinical family? Would a hospital that had previously billed for a service using a CPT code when it was part of a new technology APC trigger an expansion of its services if it bills for the same CPT code after it is assigned to a separate APC?

In addition, according to CMS's proposal, when a patient has a single encounter at an excepted off-campus HOPD, the patient could receive some services that are excepted as well as other services that are nonexcepted. We are concerned that these circumstances are not possible to track or bill in the manner proposed by CMS. Under CMS's proposal, these situations would require the hospital to bill under the OPSS using the institutional claim (UB04) for the excepted services and the physician services would be billed using the professional claim (CMS 1500) for other services at the same encounter. This would be prohibitively burdensome, particularly in the short term. The manner in which an encounter is registered determines which bill type is used –

either freestanding clinic, which directs the IT system to generate a 1500 claim, or outpatient hospital, which directs the IT system to generate a UB claim. A hospital would have no way to know that for a single visit, a service that per CMS's proposal would represent an expanded clinical family had been performed and must be billed differently.

Further, in discussing its proposed recommendations related to expansion of services at excepted HOPDs, CMS requests comment on whether it should adopt a specific timeframe during which service lines had to be billed under the OPSS prior to Nov. 2, 2015 in order for the family of services to be excepted, such as from CY 2013 through Nov. 1, 2015. **The AHA strongly opposes any policy that would establish such a specific timeframe, as this would be contrary to the plain language of BiBA.** BiBA excepts from site-neutral payment those off-campus HOPDs of a provider that had furnished covered outpatient department services before the date of enactment. The law does not place any further temporal limitations around which items and services would qualify for continued payment under the OPSS.

Change of Ownership. CMS proposes that if a hospital, in its entirety, has a change of ownership and the new owners accept the existing Medicare provider agreement from the prior owner, the hospital's off-campus HOPDs may maintain their excepted status. Further, individual excepted off-campus HOPDs would not be permitted to be transferred from one hospital to another and maintain their excepted status.

The AHA is concerned that CMS's proposal would not permit an excepted off-campus HOPD to retain its excepted status if it is individually acquired by another hospital. Often, hospitals in financial difficulty that plan to close their inpatient hospital beds will offer to transfer their HOPDs to better-performing hospitals in order to ensure that critical hospital-based outpatient services are still accessible to patients in the community. Such acquisitions may not be financially feasible if the HOPD were to lose its payment.

For instance, a member large nonprofit faith-based health system has a facility in Texas that has plans to enter into a joint venture with another hospital to acquire an excepted off-campus HOPD offering Cyberknife services, which is a non-invasive alternative to surgery for the treatment of tumors anywhere in the body by delivering beams of high dose radiation to tumors with extreme accuracy. The excepted HOPD is owned by another hospital that is closing its doors. Under CMS's proposed rule, this HOPD would not be able to be transferred to the health system without losing its excepted status.

**As noted previously, nothing in BiBA requires that CMS treat the change of ownership of individual excepted HOPDs in this way. The plain language of BiBA does not address change of ownership in any way. CMS should ensure that patients continue to have access to the services they need at the facilities where they seek treatment by protecting hospitals' and health systems' ability to acquire individual excepted HOPDs without experiencing a loss of reimbursement. We urge CMS to allow individual HOPDs to be transferred from one hospital to another and maintain their excepted status.**



Comment Solicitation for Allowing Direct Billing and Payment for Nonexcepted Items and Services in 2018. CMS requests comments in the proposed rule about developing a new billing and payment policy proposal for CY 2018. Specifically, whether an off-campus provider-based HOPD should be allowed to bill nonexcepted items and services on the professional – not institutional – claim and receive payment under the PFS, provided the HOPD meets all the applicable PFS requirements. CMS notes that under this proposal, the agency envisions that a nonexcepted HOPD would still be considered to be part of the hospital and that the hospital as a whole would continue to be required to meet all applicable conditions of participations and regulations governing its provider-based status, but, for payment purposes, the off-campus HOPD would be considered a nonhospital setting that is similar to a freestanding physician office or clinic and that is paid the same rate that is paid to freestanding offices or clinics under the PFS.

*Administrative Impediments Related to Use of the Professional Claim for HOPD Billing.* CMS asks for comment regarding whether there would be administrative impediments for hospitals billing in this way for such services. Requiring hospitals to bill using the CMS 1500 (professional claim) for nonexcepted off-campus HOPDs creates many difficult operational issues. Hospital billing systems are designed to generate the institutional claim, referred to as the UB04/837I, and not the professional claim, CMS 1500. Billing on the CMS 1500 claims requires entirely different software and processes. **It is critical that CMS’s site-neutral payment regulations continue to allow nonexcepted services in off-campus HOPD to be billed on the UB04/837I.** In addition, as noted earlier, CMS already requires hospitals to bill using a UB04/837I for certain services that are only paid at the PFS rate, such as therapy and preventive services.

The AHA believes that, in the statutory language included in BiBA, Congress signaled its intent that hospitals bill on the institutional claim, rather than the professional claim, when it referenced another “applicable payment system” being used to pay for nonexcepted items and services in off-campus provider-based HOPDs. That is, BiBA adds language to the Social Security Act at 1833(t)(21)(D) to implement site-neutral payment, stating, “Each hospital shall provide to the Secretary such information as the Secretary determines appropriate to implement this paragraph and paragraph (1)(B)(v) (which may include reporting of information *on a hospital claim* using a code or modifier).”

Further, as CMS itself notes, nonexcepted HOPDs would remain provider-based departments of the hospital and there are important implications of having their charge and cost data flow to the hospital cost report as it does today. The AHA is concerned that if the billing for these non-excepted off-campus HOPDs is on CMS 1500 claims, the information on hospital services and encounters performed in these provider-based HOPDs would be completely lost for purposes of cost allocation, settlement and other policies. This information is crucial for proper cost reporting and reconciliation to hospital ledgers for all services and departments, not just for excepted services that are paid via the OPSS and for inpatient services. It is important that the revenue for these nonexcepted off-campus HOPDs flow through the Provider Statistical and Reimbursement (PS&R) report, even if that revenue is not paid via the OPSS.

These HOPDs are different than freestanding physician practices that are owned and operated by a hospital and that bill on the CMS 1500 claims. Such physician practices are, by definition, not a provider-based department of the hospital, but rather nonhospital entities. By contrast, nonexcepted off-campus HOPDs are full-fledged provider-based departments which, although their payment may not be via the OPPS, would have costs included in the hospital general ledger and, for correct apportionment, should be included in the PS&R. Further, while it is true that some hospitals currently act as a billing service for their employed physicians' professional services (where the physicians reassign their benefits to the hospital) on the CMS 1500, this is completely different than a hospital billing for the facility's services on a professional claim. Just because a hospital knows how to bill professional services on a CMS 1500 does not mean it would be able to shoehorn the HOPD's facility services, with their years of distinct coverage and reimbursement policies and procedures, onto the professional claim, especially with the limited guidance CMS has provided and the extremely short time to implement such a feat.

There are additional concerns and complexities that would arise if CMS were to require hospitals to bill under its provider number using the CMS 1500 professional claim for nonexcepted items and services furnished in a provider-based off-campus HOPD. For instance:

- Every hospital with off-campus provider-based HOPDs would need to run dual billing systems for its excepted and nonexcepted outpatient services, one using the UB04 claim and one using the CMS 1500. The hospital's IT system would have to be altered in order to differentiate between the two. This would be even more complex for those individual patient encounters in excepted HOPDs that involve both excepted and nonexcepted services, in which case, the IT system would need to differentiate those services that would have to be billed on the CMS 1500 and those that would be billed on the UB04. Furthermore, this creates a dual billing system for Medicare only, which make this approach unwieldy, bureaucratic and very costly.
- There would be additional administrative burden placed on the Medicare Administrative Contractors, which would have to submit remittances to hospitals under two systems.
- Medicare beneficiaries would receive two different bills from the hospital, which would include different copayment amounts; one for services billed on a UB04 and one for services billed on a CMS 1500. Further, if the patient encounter involved physician services, there would be a third bill with a third patient copay.
- Claims for Medicare outpatient hospital services provided within 72 hours of admission are rolled into the inpatient claim. Currently, CMS looks for an overlap of hospital claims under the same provider number. How would CMS be able to find such overlap between the inpatient UB04 and the outpatient CMS 1500 claims? How would CMS combine the claims if the CMS 1500 service was billed with physician's billing number? Would the payment window apply if the physicians are not employed by the hospital?

- There would be downstream effects for secondary supplemental payers, including Medicaid and commercial insurers. We are concerned that state Medicaid agencies would not be able to handle cross-over claims for beneficiaries who are dually eligible. We have similar concerns about secondary supplemental payers being able to handle hospital outpatient services being billed on both institutional and professional claims.
- Any other program that uses the hospital outpatient data set for public health, quality or price transparency analyses would be negatively impacted by this change. Programs such as state databases that compare costs across hospitals, would have to contend with getting multiple bills for the same encounter or a single bill that does not cover the entire encounter.
- There may be implications for the Health Insurance Portability and Accountability Act (HIPAA) transaction standards. In particular, the 837P, the professional claim, is not intended to be used for institutional services, such as facilities enrolled as provider-based departments of a hospital. Rather, institutional services, such as HOPD services, are intended to be billed on the 837I claim. Furthermore, we are aware that the National Uniform Billing Committee (NUBC), the data content organization for the HIPAA transaction standards, has sent CMS a [letter](#) expressing concern that it was not consulted prior to CMS proposing a new interpretation of the transaction standard. In its letter, the NUBC indicates its disapproval of any efforts by CMS that force an institutionally-based facility to switch billing instruments for the technical services away from an institutional claim. The AHA agrees.

*Applicable Payment System in CY 2018.* While CMS does not formally propose an applicable payment system for nonexcepted items and services in off-campus HOPDs in CY 2018, it notes that it is “actively exploring options that would allow off-campus PBDs to bill for these services under another payment system, such as the MPFS, and be paid at the applicable rate under such system beginning in CY 2018.” Further, the agency envisions that “for payment purposes, the off-campus HOPD would be considered a nonhospital setting that is similar to a freestanding physician office or clinic and that is paid the same rate that is paid to freestanding offices or clinics under the MPFS.” Thus, it seems that CMS is considering proposing the PFS as the applicable payment system for nonexcepted items and services.

**The AHA does not agree that the PFS should be the sole non-OPPS payment system considered for CY 2018.** The PFS would neither provide accurate payments to HOPDs for nonexcepted services, nor minimize burden on hospitals or Medicare beneficiaries; it also does not cover many services provided in HOPDs. Indeed, there are certain services, such as observation, critical care and partial hospitalization that are only covered under the OPPS. In addition, if payment under the PFS necessitates that hospitals bill for their services on the professional claim, the CMS 1500, then, as we note previously, we would find this approach unacceptable. Furthermore, because the PFS was created to account for physicians’ professional costs, not the facility costs borne by hospitals, there are many services for which the PFS payment rates, both in the facility and the nonfacility settings, are inadequate. The ambulatory surgical center (ASC) payment rates may be a better fit for paying for some surgical services in

nonexcepted HOPDs. However, even this system is problematic because there are many surgical services commonly performed in HOPDs that are not covered in the ASC setting.

**The AHA believes that because Congress did not specify an applicable payment system, the agency is free to choose any of the existing Part B payment systems, alone or in combination, or even to create an entirely new Part B payment system designed only for nonexcepted items and services.** Therefore, during CMS’s delay of its implementation of the BiBA site-neutral provisions, we recommend it solicit stakeholder input – through listening sessions, town hall meetings and existing advisory committees – and carefully and thoroughly consider its options in order to develop a well-thought out, vetted and fair payment system for nonexcepted items and services in off-campus HOPDs.

### **ADDITIONAL COMMENTS ON CMS’S BIBA SITE-NEUTRAL PROPOSALS**

Definition of Excepted Off-campus Provider-based Department. BiBA excepts from site-neutral payment any provider-based off-campus HOPD “that was billing under this subsection [*OPPS*] with respect to covered OPD [*outpatient department*] services furnished prior to the date of enactment [*Nov. 2, 2015*] of this paragraph” (Emphasis added). CMS proposes that only those off-campus HOPDs that *had submitted a bill* for covered HOPD service prior to Nov. 2, 2015 would be excepted. **However, the AHA believes that the best reading of the statutory language is that, in order for an off-campus HOPD to be excepted, the covered outpatient department services must have been furnished prior to Nov. 2, 2015.**

First, a plain reading of the statute’s language reveals that the clause “covered OPD services furnished” is in closer proximity to “prior to the date of enactment” than “billing under this subsection.” That is, we believe that “prior to the date of enactment” modifies “furnished” but not “billing under this subsection.” The AHA believes that this proximity has meaning, leading to our conclusion that it is the date services are furnished, rather than the date the furnished service is billed, which must be prior to the date of enactment. Second, we note that our interpretation also is consistent with the overall purpose of this provision, which is to except from site-neutral payment those off-campus HOPDs that were already in operation as of the date of the provision’s enactment. Clearly, HOPDs that were furnishing covered outpatient department services as of Nov. 1, 2015, regardless of when they submitted a bill, were in operation as provider-based HOPDs before the statute was enacted.

This distinction in interpretation is important because we are aware of a number of hospitals that submitted updated Medicare enrollment information for their off-campus HOPD and started furnishing services prior to Nov. 2, 2015, but had not yet submitted a bill for these services by that date. These delays in billing had many causes, such as delays by the CMS regional offices in processing or approving their enrollment information, in state licensing, or due to standard billing practices or periodic (monthly) billing requirements. For instance, one member New York hospital opened and began furnishing services to Medicare beneficiaries at an off-campus provider-based cancer infusion center in October 2015. Because infusion services are generally billed monthly, the provider did not submit a bill for Medicare for these services until mid-

November 2015. Additionally, a hospital in California opened its doors in October 2015, following a successful state survey. However the license was not issued by the California Department of Public Health until Nov. 1, 2015. While the hospital had seen Medicare beneficiaries beginning in October, it could not have appropriately billed Medicare for services until after Nov. 1. Nor would it have been plausible to have billed Medicare the same day service was provided as most providers bill Medicare every seven or 14 days.

It is clear in these circumstances that such off-campus HOPDs were in operation, furnishing covered outpatient departments services prior to BiBA's enactment date and, therefore, deserve to be excepted from the site-neutral payments. **We strongly recommend that, in the final rule that CMS use the date of service, rather than the date a furnished service is billed, to determine whether an off-campus HOPD is excepted. That is, we recommend that CMS finalize a policy that allows any off-campus HOPD to continue to be paid under the OPSS as long as it had furnished a covered outpatient department service prior to Nov. 2, 2015.**

Exemption of Items and Services Furnished in a Dedicated Emergency Department (ED). **The AHA supports CMS's proposed policy that all services furnished in an ED, whether or not they are emergency services, would be exempt from application of the site-neutral payment rates and, thus, would continue to be paid under the OPSS.** We believe that this approach is consistent with the requirements in BiBA and with Congress's intent.

On-campus Locations. **The AHA supports CMS's proposal to retain the existing regulatory definition of "campus" as "the physical area immediately adjacent to the provider's main buildings, or other areas and structures that are not strictly contiguous to the main buildings but are located within 250 yards of the main buildings, and any other areas determined on an individual case basis, by the CMS regional office, to be part of the provider's campus."** Given the important new implications of being located on a hospital's campus, we agree that it is advisable to continue to use the current definition of facilities that are considered to be on-campus versus off-campus, including the use of both the 250 yards rule, as well as allowing the CMS regional offices to continue to provide case-specific discretion for making such determinations. Such discretionary authority is important in circumstances in which a hospital and its related facilities are located in an area that includes unusual geographic features, such as mountains, highways and bodies of water, which might benefit from the regional office's existing discretionary authority to determine which facilities are on the hospital's main campus. **In addition, we support CMS's proposal that off-campus provider-based department must be located at or within the distance of 250 yards from any point of a remote location of a hospital facility.**

Treatment of New or Relocated Hospital-based Partial Hospitalization Programs (PHPs). **The AHA recommends that new hospital-based PHPs that open on or after Nov. 2, 2015, as well as excepted PHPs that relocate or expand, be permitted to continue to bill under OPSS at the hospital-based PHP rate.** The PHP benefit serves an especially vulnerable population, as an important intermediate service between outpatient, office-based visits and inpatient psychiatric care. It is a critical, cost-effective level of care for persons living with mental illnesses. Further, there is no comparable service to PHP provided in any other setting, including a physician office,

and there is no other appropriate payment mechanism, other than the OPPS, for this service. **Unless PHPs are excepted from the site-neutral payment policy, CMS would be directly undermining a statutory Medicare benefit that has been effective in reducing hospitalization and lowering the overall cost of caring for Medicare beneficiaries living with mental illnesses.**

For example, one member nonprofit health care network provides mental health services through partnerships with other rural southwest Louisiana health care providers. Through these partnerships, this organization works to address the unique struggles facing rural communities related to the diagnosis and treatment of mental illness. The impact of BiBA on this organization and other mental health providers is to essentially eliminate the ability of psychiatric hospitals to open mental health outpatient departments in rural areas where there is an urgent need for such services. Many of the patients served by outpatient psychiatric departments, such as PHPs, cannot drive or arrange transportation to the main psychiatric hospital, which can be located as far as 35 miles away, to receive these services. Therefore, placing of mental health outpatient departments in rural areas is a way to meet the mental health needs of underserved patients. As a result, the health care network reports that proposed site-neutral payment policy would have a profoundly negative impact on mental health patients' access to care.

CMS acknowledges that the proposed rule would effectively end the existing PHP billing model. However, the agency's proposed solution, that nonexcepted off-campus PHPs enroll and bill as community mental health centers (CMHC) under OPPS, is not feasible. CMHCs require separate certification, operate under separate conditions of conditions of participation, and operate in a way that is distinctly different from an off-campus hospital-based PHP. CMS itself has acknowledged the distinct advantages that hospital-based PHPs provide over CMHC PHPs. In a 2009 CMS-commissioned report, RTI International found that hospital-based PHPs: (1) offer better continuity of care to patients who have been discharged from an inpatient unit from the same provider; (2) are better at information sharing; (3) have easier access to more support staff, nutritionists, nurses and psychiatrists; and (4) have an advantage over CMHC-based program, in timely and safe readmission to an inpatient unit.<sup>1</sup> Thus, CMS's proposed solution overlooks not only the essential structure of hospital-based PHPs, but also their built-in benefits.

Furthermore, CMS's proposal would have another significant and harmful impact on the delivery of behavioral health services. That is, application of the PFS to nonexcepted off-campus HOPDs would require hospitals to hire additional physicians in order to meet the PFS supervision requirements and completely restructure residency programs so that attending physicians meet the requirements to provide "personally performed services" to obtain reimbursement under the PFS. This would radically alter the residency training programs and impose extraordinary new costs to hire attending supervisors to see patients with trainees.

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<sup>1</sup> Leung M, Drozd E, Maile J, "Impacts Associated with the Medicare Psychiatric PPS: A Study of Partial Hospitalization Programs," Prepared for CMS by RTI International (February 2009).

In addition, there is no physician-based alternative to PHPs. The PHP benefit is intended to be the intermediate step between acute inpatient psychiatric care and physician-based services. Similarly, CMHC-based PHPs, which are intended to address a unique community need, are required to operate under a separate set of conditions of participation and are separate and distinct from the hospital-based PHP benefit.

Finally, we are concerned that eliminating the incentive for hospitals to establish new hospital-based PHPs to serve these vulnerable patient populations would result in these patients seeking care in already overcrowded EDs. There is significant evidence that ED care is a very costly way to care for patients experiencing a mental health crisis.<sup>2</sup> In a health reform environment that values continuity of care, hospital-based PHP has great value as a system that provides patients with cost-effective treatment at the most appropriate level, allowing timely and smooth transition to the next level of care.

**We strongly recommend against forcing hospital-based PHPs into a payment system that was not designed for that purpose and, in the process, interrupting patient continuity of care and potentially driving vulnerable patients in crisis to less effective care in already-overcrowded EDs. Instead, CMS should allow new off-campus PHPs, as well as excepted PHPs that relocate or expand, to continue to bill under OPSS at the hospital-based rate.**

## **OTHER PROPOSED CHANGES TO OPSS PAYMENT POLICY**

### **PROPOSED CLINICAL DIAGNOSTIC LABORATORY TEST PACKAGING POLICIES**

Proposed “Unrelated” Laboratory Test Exception. Under current policy, CMS’s policy to package clinical diagnostic laboratory tests have a number of exceptions. One of these exceptions is for unrelated laboratory tests defined as “tests on the same claim as other hospital outpatient services, but are ordered for a different diagnosis than the other hospital outpatient services and are ordered by a different practitioner than the practitioner who ordered the other hospital outpatient services.” Hospitals bill and receive separate payment for unrelated laboratory tests using “L1” modifier on the claim. CMS proposes to discontinue the unrelated laboratory test exception (and the “L1” modifier) on the basis that hospitals have found it difficult to determine when a laboratory test has been ordered by a different physician and for a different diagnosis than the other services reported on the same claim and that a different diagnosis and different ordering physicians do not necessarily correlate with the relatedness of a laboratory test to the other HOPD services that a patient receives during the same hospital stay.

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<sup>2</sup> Abid Z., *et al*, “Psychiatric Boarding in U.S. EDs: A multifactorial problem that requires multidisciplinary solutions”, George Washington University Urgent Matters Policy Brief (noting the need for additional sources of outpatient mental health services in the community) (June, 2014).

**The AHA supports CMS’s proposal in this particular context. We agree that hospitals found the use of the L1 modifier to be confusing and burdensome, especially because it required manual handling of such claims. However, we do not want our comments to be construed as being generally supportive of the packaging of unrelated services.** Indeed, CMS’s rationale for this policy articulates that the associated laboratory services are not “unrelated” simply because they were ordered for a different diagnosis and different practitioner than for other outpatient hospital services. CMS indicates that in these circumstances, the laboratory services being billed are not necessarily unrelated to the service into which it is being packaged because “most common laboratory tests evaluate the functioning of the human body as a physiologic system and therefore relate to other tests and interventions that a patient receives. Also, it is not uncommon for beneficiaries to have multiple diagnoses, and often times the various diagnoses are related in some way.”

**In addition, we reiterate our general opposition to packaging services unrelated to another outpatient hospital service being billed on the same claim.** The purpose of packaging is to make a single payment for all services and supplies that are “integral, ancillary, supportive, dependent, or adjunctive to other hospital outpatient services.” When a service is unrelated to another service, it does not meet the packaging criteria and should always be paid separately.

**Furthermore, even when services meet the criteria for packaging, the AHA generally believes that packaging makes policy sense only in those circumstances where the packaged item is low cost and/or commonly furnished with the principal procedure, such that its costs will be reflected in the data that CMS uses for rate setting.** In circumstances in which a service proposed to be packaged has a significantly higher cost than the principal service into which its costs would be packaged and is not commonly furnished with the principal service that the beneficiary is receiving, the claims data will not reflect the cost of the ancillary procedure. **In these circumstances, the ancillary service should continue to be paid separately to avoid the potential for a high-cost service from being packaged with a principal service that may be of comparable or even less cost than the ancillary service.**

Impact of Change in Unrelated Laboratory Packaging. CMS estimates that its proposed policy to discontinue the use of the L1 modifier on claims that identify unrelated laboratory tests and instead to package all laboratory tests would have a 0.03 percent impact on OPPS payment. Therefore, CMS proposes to add an additional 0.03 percent to OPPS payments to account for this proposed policy. As the agency did not provide any detail on how it arrived at this estimate, the AHA conducted its own analysis in an attempt to replicate CMS’s estimate. **Based on this analysis, we believe that CMS’s estimate of the impact of packaging unrelated laboratory costs may be significantly low.** While CMS does not quantify the dollar amount that the proposed 0.03 percent add-back represents, we estimate it to be between \$15 million and \$19 million. However, in the AHA’s analysis (attached), we estimate that the proposed policy would have a greater impact, assuming that payment impacts correlate with cost, in the range of 0.06 percent to 0.09 percent. This represents an impact of between \$39 million and \$43 million in additional OPPS costs, double or triple the estimated impact of 0.03 percent reported by CMS. **The AHA urges CMS to review its methodology to ensure that payment factors are set properly to account correctly for the costs of its proposed policy.**



Proposed Expansion of Packaging Exception for Advanced Diagnostic Laboratory Tests (ADLTs). **The AHA supports CMS's proposal to assign status indicator "A" to laboratory tests designated as ADLTs so that they would be paid separately under the CLFS.** We agree that ADLTs, like molecular pathology tests, are relatively new and may have a different pattern of clinical use than more conventional laboratory tests. As a result, they may be less tied to a primary service in the outpatient department than other types of laboratory tests.

## **PROPOSED CHANGE IN "Q1" AND "Q2" CONDITIONAL PACKAGING STATUS INDICATORS LOGIC**

CMS invites comment on its proposal to change the logic for conditional packaging status indicators Q1 and Q2 so that packaging would occur at the claim level, instead of based on the date of service. The agency intends to align these status indicators' logic with other conditional packaging status indicators that package at the claim level. The result of this proposed change would be that items and services that are provided during a hospital stay that may span more than one day would be packaged.

While this proposal may be reasonable for many Q1 and Q2 status indicator services, it does not make sense for repetitive services that are repeated over a span of time and billed by hospitals on a monthly claim. Certain repetitive services are assigned status indicator Q1, most notably pulmonary rehabilitation services. For example, if CMS's proposed policy were applied to pulmonary rehabilitation, a claim that included an entire month's worth of pulmonary rehabilitation services, without any other separately billable services, would result in payment of only one instance of pulmonary rehabilitation.

The AHA recommends that CMS carefully consider the potential unintended consequences of claims level packaging on Q1 and Q2 repetitive services. **As a general policy, we recommend that any recurring services assigned a Q1 status indicator have their status indicator changed to S, so that these services would be separately paid. In particular, we request that CMS change the status indicator for pulmonary rehabilitation services to S.**

Anatomic Pathology Packaging Policy. **The AHA supports the recommendation made by the Advisory Panel on Hospital Outpatient Payments (HOP Panel) at its Aug. 22 meeting that CMS should create composite APCs<sup>3</sup> for pathology services that are billed on a claim without a separately payable service.** Anatomic pathology services, represented by Current Procedural Terminology (CPT) codes 88300 through 88361, are used to detect cancer in biopsy specimens collected from patients. Hospitals often receive multiple biopsy specimens for a single date of service for evaluation in the hospital laboratory. Each specimen must be analyzed independently for accurate diagnosis of the potential type and specific location of cancer.

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<sup>3</sup> Composite APCs provide a single payment for groups of services that are typically performed together during a single clinical encounter and that result in the provision of a complete service.

Currently, when multiple conditionally packaged (status indicators Q1 and/or Q2) pathology services are performed and billed on the same date without a separately payable APC service, Medicare's outpatient code editing logic limits payment only to the single highest-paying code, regardless of the number of services provided or specimens tested. None of the other services provided on that date of service are paid. In the proposed rule, CMS would expand this packaging to Q1 and Q2 services that are furnished on the same claim without a separately payable APC service.

The potential consequences of this "ancillary only" packaging policy is twofold. First, it results in inadequate reimbursement when multiple conditionally packaged pathology services are billed on the same claim. Second, it introduces potential rate-setting anomalies resulting from the conditional packaging logic applied to frequent and common sets of multiple pathology services furnished together. We note that beyond anatomic pathology services, this type of packaging concern also arises for other Q1 and Q2 services, such as respiratory services, cardiology services, X-ray services and allergy testing services, that are commonly furnished together without other separately payable APC service and which would benefit from the creation of composite APCs.

**Therefore, the AHA supports the HOP Panel's recommendation that CMS create composite APCs for pathology services that are billed without a separately payable service. This would not only promote adequate reimbursement of pathology services but would also promote accurate rate-setting for pathology services. In addition, the AHA urges CMS to consider creating other ancillary services composite APCs.**

## **PROPOSED CHANGES TO THE COMPREHENSIVE APCS (C-APCS)**

Impact of Adding Relatively Low-cost Procedures to the C-APC Logic. The AHA is concerned that CMS may not be fully considering the impact of adding relatively low cost (below \$2,227) procedures to the C-APC logic. There are more than 750 HCPCS codes proposed to move from status indicator T (separate APC payment) to J1 (primary C-APC procedure) for 2017, with proposed payment rates under \$2,227. More than 170 of these have a 2017 proposed payment rate that is less than the 2016 payment rate. However, the current structure of the OPSS payment methodology establishes the C-APCs as the highest cost bundle under which all other procedures (e.g., status indicator T, S and J2 procedures) on the same claim with a status indicator J1 principal procedure are packaged into the payment rate for the J1 procedure.

While CMS establishes the J1 C-APC rates using this methodology and thereby captures all the related costs under the C-APC, low-volume combinations of services that are very high cost will generally not make a material difference in the geometric mean cost of the C-APC. Specifically, in circumstances where a status indicator T service is higher cost and not commonly furnished with the principal C-APC service, the payment rate will not adequately represent the cost of these higher cost services.

**Since CMS's policy is that the status indicator J2<sup>4</sup> C-APC services are always packaged into a J1 C-APC, the AHA recommends that a payment rate greater than the J2 C-APC rate for the given year should be established as the minimum threshold for a J1 C-APC. For CY 2017, the status indicator J2 C-APC, Comprehensive Observation Services, proposed payment rate is \$2,227.** We believe the proposed expansion of C-APCs to include low-cost procedures – that is, C-APCs with payments less than \$2,227 – is inappropriate because many of the claims included with HCPCS codes that would be classified under these new APCs include other high-cost procedures assigned to status indicator T that have APC payment rates that exceed the C-APC payment rate by more than \$1,000. This leads us to the conclusion that these claims indicate that the proposed J1 HCPCS codes in these C-APCs are not always the principal service and that, in fact, they frequently are ancillary or supportive to services performed in conjunction with a higher cost procedure.

**The AHA also recommends that CMS consider making changes to its methodology to account for scenarios where a high-cost status indicator S or T procedure is present on a claim with a C-APC.** For instance, we recommend that CMS evaluate the addition of complexity adjustments for certain combinations of high-cost status indicator S or T procedures performed in conjunction with C-APCs. In particular, CMS should consider the issue of high-cost new technology APCs, especially those with payments exceeding \$25,000. These very high-cost new technology procedures should not be bundled into a low-cost C-APC. Instead, CMS should consider excluding new technology APCs from the C-APCs or establish the very high cost new technology APCs as C-APCs.

**The AHA supports CMS's proposal to discontinue the requirement that prevents a code combination that meets the frequency and cost complexity adjustment criteria from receiving a complexity adjustment if it creates a two-times rule violation in the higher level receiving APC. However, we request that CMS further refine this change not only to remove the restriction that would prevent the code combination from receiving a complexity adjustment, but also to move the code combination up an additional level in the clinical family (if available) when the cost of the code combination exceeds the two-times rule in the receiving APC.**

For example, the Breast Surgery clinical family has four levels of C-APCs. There are three code combinations that exceed the frequency threshold, the primary APC assignment of APC 5092 (Level 2 Breast/Lymphatic Surgery and Related Procedures) two-times rule cost threshold of \$8,205.85, and also the complexity adjusted APC assignment of APC 5093 (Level 3 Breast/Lymphatic Surgery and Related Procedures) two-times rule cost threshold of \$11,737.76. **The AHA recommends that CMS move these three code combinations, as displayed in the table below, to APC 5094 (Level 4 Breast/Lymphatic Surgery and Related Procedures).**

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<sup>4</sup> The assignment of status indicator J2 to a specific combination of services performed in combination with each other allows for all other OPPS payable services and items reported on the claim (excluding services that are not covered HOPD services or that cannot by statute be paid for under the OPPS) to be deemed adjunctive services representing components of a comprehensive service and resulting in a single C-APC payment for the comprehensive service based on the costs of all reported services on the claim.

These are the only code pairs in the proposed complexity evaluation table (Table 1 below) that exceed both the two-times cost threshold for the primary APC and the proposed complexity adjusted APC. In addition, all four codes involved are newly proposed C-APCs. As CMS expands the C-APC logic, the methods for complexity adjustment must be evaluated and modified to appropriately reflect the added C-APCs.

**Table 1**

Primary HCPCS Code	Secondary HCPCS Code	Frequency	Code Pair Geometric Mean Cost	Cost Threshold for primary APC 5092	Cost Threshold for proposed complexity adjusted APC 5093	Geometric Mean Cost for APC 5094
19307	19340	45	\$13,632.17	\$8,205.85	\$11,737.76	\$10,219.34
19340	19303	212	\$13,121.63	\$8,205.85	\$11,737.76	\$10,219.34
19340	38525	68	\$11,971.78	\$8,205.85	\$11,737.76	\$10,219.34

**C-APC for Allogeneic Hematopoietic Stem Cell Transplantation (HSCT). The AHA supports the HOP Panel’s recommendation that CMS proceed with the creation of a C-APC for allogeneic HSCT.** However, we are concerned with CMS’s use of all claims to establish the payment rate for the proposed C-APC. A correctly coded claim for allogeneic HSCT includes charges that reflect the costs for donor search and cell acquisition reported by providers using revenue code 819 (or, in the future, through the newly proposed revenue code 815) and for the actual stem cell transplantation procedure (CPT code 38240). Unfortunately, it appears that CMS has created the C-APC rate using all claims, including those missing donor search and cell acquisition charges. CMS’s billing guidance instructs providers to report donor search and acquisition costs under revenue code 819 on the same date of service as the stem cell transplant (CPT code 38240) is billed. Despite CMS’s guidance, providers do not always bill correctly and accurately for both of the components of this overall service.

**To facilitate accurate reporting in the future, the AHA recommends that CMS create a code edit that requires the presence of the donor acquisition revenue code and the stem cell transplant code on the same date of service in order to ensure that CMS receives accurate and complete claims with which to set the C-APC rate.** Claims that fail this edit should be returned to the provider.

**In the meantime, the AHA recommends that CMS use only correctly coded claims, i.e., those that include both CPT code 38240 and charges under revenue code 819, to set the rates for the newly proposed C-APC for allogenic stem cell transplantation.**

## **BLOOD AND BLOOD PRODUCT CODING**

We agree with CMS that a thorough examination of the current set of HCPCS P-codes for blood products is warranted as these HCPCS P-codes were created nearly a decade ago. Since that time, clinical processes have evolved to ensure the safety of the blood supply. We believe that HCPCS codes should properly reflect current product descriptions while at the same time minimize the reporting burden. We recommend CMS convene a stakeholder group including hospitals, blood banks, the American Red Cross and others to discuss a framework to systematically review and revise the HCPCS codes for blood products. In the interim, we suggest that CMS consider the following general recommendations when exploring how to best improve the HCPCS codes for blood products:

- **Hospitals must retain the ability to bill for blood products using unique HCPCS codes that individually identify each product.** We believe that the HCPCS codes for blood products should continue to individually identify different blood products based on processing methods, since these methods result in blood products that are distinguishable and used for distinctive purposes. Similar to the way that hospitals bill for other products covered by Medicare Part B, we urge CMS to retain individual HCPCS codes for unique blood products with significant therapeutic distinctions. We are concerned that providers would be confused and overly burdened if CMS were to establish a different billing protocol for blood products. **We do not believe that creating modifiers to be applied to the existing HCPCS P-codes, instead of creating unique HCPCS codes, is a viable solution as modifiers require manual assignment and tend to be confusing and therefore result in being inadvertently omitted.** Recent requests for new HCPCS P-codes at the June 2016 CMS HCPCS Public Meeting to identify "bacteria tested" platelet units have resulted in preliminary decisions to create HCPCS modifiers instead of new HCPCS P-codes.
- **CMS should consider establishing a “not otherwise classified” code for blood products.** Once more specific, clinically different, HCPCS P-codes are created, there should also be a mechanism for hospitals to begin immediately billing for a new blood product that is not captured by an existing P-codes. This would be similar to the existing codes for other substances (e.g., J-codes for drugs and biologicals). We believe that a “not otherwise classified” code is essential for ensuring that payment policies are able to accommodate important new technologies and new products, and that Medicare beneficiaries have timely access to these life-saving innovative technologies and products.

## **SOLICITATION OF PUBLIC COMMENTS ON THE POSSIBLE REMOVAL OF TOTAL KNEE ARTHROPLASTY (TKA) FROM THE INPATIENT-ONLY LIST**

CMS seeks public comments on whether it should remove TKA or total knee replacement, CPT code 27447, from the inpatient-only list. In addition, the agency asks for public comment on

several related questions, including how CMS could modify the Comprehensive Care for Joint Replacement (CJR) and the Bundled Payment for Care Improvements (BPCI) initiatives if the TKA procedure were to be moved off the inpatient-only list. **The AHA opposes the removal of TKA from the inpatient only list for 2017 and urges CMS to take extreme caution if it contemplates this change in future years. We do not believe it is clinically appropriate and are further concerned that it could put the success of the CJR and BPCI programs at risk.**

TKAs remain complicated, invasive surgical procedures. While they may be successfully performed on an outpatient basis for non-Medicare individuals, we do not believe it is appropriate for the Medicare population. Nearly half of all Medicare beneficiaries live with four or more chronic conditions and one-third have one or more limitations in activities of daily living that limit their ability to function independently, which will make even a simple procedure more complicated. In addition, spinal anesthesia is often used for TKAs and waiting for full sensation to return can take hours. Finally, pain management, particularly in the immediate postoperative period, remains a challenge. Management of postoperative pain is best controlled in the inpatient setting.

With regard to CJR and BPCI, as the agency notes, shifting the less medically complex Medicare TKA population to the outpatient setting would increase the risk profile of the inpatient Medicare TKA population. This would, in turn, create an apples-to-oranges comparison within bundling programs when evaluating hospitals' actual expenditures versus their historical target prices. Performance under the programs would be inappropriately negatively impacted, potentially to a large degree. Notwithstanding our clinical concerns, below, we put forth several suggestions for how the agency could potentially modify the CJR and BPCI programs to attempt to account for this change; however, these changes would be meaningful and complex and require much more policy development, stakeholder feedback, and implementation time for CMS and program participants.

**Our first suggestion is for the agency to incorporate a comprehensive risk-adjustment methodology into the CJR and BPCI programs.** This would ensure that actual and historical episode spending is adjusted to reflect comparable patient populations. We have previously urged CMS to incorporate risk adjustment into the CJR program; its unwillingness to do so remains perplexing to us. Specifically, the agency stated that it did not incorporate risk adjustment into the program because it does not believe that a sufficiently reliable approach exists, and that there is no current standard on the best approach. However, the agency just last year finalized a risk-adjustment methodology as part of its measure of "Hospital-Level, Risk-Standardized Payment Associated with a 90-Day Episode of Care for Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA)," which will be included in the inpatient quality reporting program. This measure's risk-adjustment methodology accounts for many factors that are both beyond hospitals' control and also affect their performance on the measure, including type of procedure, age, obesity and the presence or absence of many different chronic conditions, such as chronic heart failure and diabetes. We note that while it has many shortcomings, not the least of which is that it applies to both TKA and THA, this methodology certainly provides a starting point from which CMS could proceed in developing an appropriate adjustment.

**CMS also may wish to evaluate including *outpatient* TKA in the CJR and BPCI programs.**

To do so, it could, for example, reimburse for this procedure at the outpatient APC rate, but substitute the relevant inpatient Medicare-Severity Diagnosis-Related Group (MS-DRG) rate when calculating a participant hospital's actual episode spending. To ensure a level playing field, CMS also would need to specify that TKA could only be performed in an HOPD – not in an ASC. Many additional considerations also would need to be evaluated, such as which quality measures would apply to participant hospitals and whether there would be sufficient information on the outpatient claim to assign the appropriate MS-DRG (i.e., the Major Joint Replacement *with* Major Complications MS-DRG vs. the Major Joint Replacement *without* Major Complications MS-DRG).

**OBSERVATION HOURS CARVE-OUT POLICY**

**The AHA recommends that CMS eliminate the current requirement that hospitals “carve out” from its count of observation hours the time involved in furnishing other diagnostic or therapeutic services that also require active monitoring.** Carving out this time is unnecessary under current payment policy and also burdensome for hospitals as it requires manual estimation and recording of the time required to complete each separate service. This policy made sense when hospitals' payment for observation was based on the hours of observation furnished and other services furnished in conjunction with observation were separately paid under the OPSS. However, currently all observation services are packaged and, with the advent of C-APC 8011, the comprehensive observation services APC finalized in CY 2016, in most cases, diagnostic or therapeutic services furnished in conjunction with observation are now included in C-APC 8011 and no longer separately paid. Further, CMS itself has decided to disregard this “carving out” of time from observation services in its final policy for implementing the Notice of Observation Treatment and Implication for Care Eligibility (NOTICE) Act. That is, in determining whether a hospital has furnished more than 24 hours of observation services to a Medicare beneficiary (thus, triggering the NOTICE Act requirement to notify the patient about their outpatient status and its implications), CMS instructed hospitals to disregard this notion of “billable hours” and instead directed hospitals to count the time directly as clock hours from the initiation of observation services.

**OUTPATIENT QUALITY REPORTING (OQR) PROGRAM**

CMS proposes to add seven new measures to the CY 2020 OQR program – hospital admissions and ED visits for outpatient chemotherapy patients, hospital visits following outpatient surgery, and five measures derived from a new Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems survey (OAS CAHPS).

**FOCUSING THE OQR ON MEASURES THAT MATTER**

**The AHA continues to urge CMS to streamline and refocus the OQR program and all of its**

**other programs on measure sets that align with concrete national priority areas. This will encourage better integration of care across the entire health care system.** America's hospitals remain committed to the foundational goals of the OQR program – to provide the public and hospitals with *accurate* and *comparable* information for improving quality on *important* areas. For this reason, we remain concerned that measures have proliferated in the OQR and other CMS programs without a well-articulated link to national priorities or goals. As a result, many measures increase the burden of collecting and analyzing data, without adding significant value to care. Compounding the dilemma, private payers and other regulatory bodies require the reporting of yet additional measures.

Since the program's inception, the number of OQR measures has more than doubled from 11 measures in CY 2009 to the 32 proposed measures for CY 2020. The varied measure set assesses topics ranging from ED throughput and cataract care to hospital visits following colonoscopies. When considered in isolation, many OQR measures appear to address compelling quality issues. For example, given the high volume of colonoscopies performed, it may seem reasonable for CMS to adopt OP-32 to measure the re-hospitalization rate following such procedures. Yet, the data CMS cited to support the addition of OP-32 to the OQR suggests the hospital visit rates after outpatient colonoscopy range from 0.8 to 1.0 percent in the seven to 14 days after the procedure. Certainly, hospitals aim to avoid unnecessary hospitalizations after colonoscopies. But the relative infrequency of such re-hospitalizations suggests the attention and effort garnered from the inclusion of OP-32 in a national program like the OQR may be better spent on other topics with a clearer and more pressing need for improvement.

**The AHA stands ready to work with CMS and all other stakeholders to streamline and focus the measures in the OQR and all other measurement programs on measures that matter.** To provide a starting point for this vital effort, the AHA has engaged hospital leaders in efforts to identify high priority hospital measure topics. In 2014, the AHA Board of Trustees approved a list of 11 hospital measurement priority areas. That list was updated in July 2016 and is provided below.

#### **AHA Identified Priority Measurement Areas**

1. Patient Safety Outcomes
  - Harm Rates
  - Infection Rates
  - Medication Errors
2. Readmission Rates
3. Risk Adjusted Mortality
4. Effective Patient Transitions
5. Diabetes Control
6. Obesity
7. Adherence to Guidelines for Commonly Overused Procedures
8. End of Life Care According to Preferences
9. Cost per Case or Episode of Care



10. Behavioral Health

11. Patient Experience of Care/Patient Reported Outcomes of Care

Hospital leaders believe using well-designed measures in these 11 areas in national measure programs would most effectively promote better outcomes and better health for the patients they serve. However, having measures addressing the right topics is only part of the solution – the particular measures also must be methodologically sound, reliable, accurate and actionable. Moreover, hospital leaders also understand the list of priority areas will evolve over time, and thus recommend “retiring” areas where sufficient progress has been achieved, and replacing them with new core areas that address emerging issues. To provide a strategic grounding for ongoing discussions about measurement priorities and specific measures, the AHA Board of Trustees also approved a list of seven strategic principles for selecting measures that was developed with extensive input of hospital leaders.

**AHA Principles for Measures to be Included in Hospital Payment and Performance Systems**

1. Provider behavior must influence the outcome(s) being measured;
2. Measures must have strong evidence that their use will lead to better care and outcomes;
3. Measures should be used in programs only if they reveal meaningful differences in performance across providers, although some may be retained or re-introduced to reaffirm their importance and verify continued high levels of importance;
4. The measures should be administratively simple to collect and report, and to the greatest extent possible, be derived from electronic health records data;
5. Measures should seek to align the efforts of hospitals, physicians and others along the care continuum, and align with the data collection efforts of the other providers;
6. Measures should align across public and private payers to reduce unnecessary data collection and reporting efforts; and
7. Risk adjustment must be rigorous, and account for all factors beyond the control of providers, including socioeconomic factors where appropriate. In addition, adjustment methodologies should be published and fully transparent.

To provide a “proof of concept” of how the 11 priorities and the principles for selection might be applied, AHA reviewed all of the approximately 90 measures in CMS’s inpatient quality reporting and OQR programs. While some of the existing measures are in line with these principles and the priority areas that were identified, most were not. Appendix A provides more detail on the measures the AHA recommends for retention, and how they map to our 11 measurement priority areas. With respect to the OQR, the AHA believes that only eight OQR measures should be retained, and all but one of those eight likely would require significant modifications to improve their reliability and accuracy.

In considering CMS’s measure proposals in this rule, we appreciate that all seven proposed measures appear to align with AHA-identified measure priorities. The two hospital admission measures align with the priority topics of readmission rates and effective patient transitions,

while the OAS CAHPS addresses patient experience of care. **Nevertheless, all seven measures have significant conceptual and methodological issues that must be addressed before they are ready for use in the OQR. Indeed, only one of the seven measures has been endorsed by the National Quality Forum (NQF), providing little insight into whether the measures are accurate and fair representations of hospital performance. Furthermore, we believe CMS should assess all seven proposed measures for the impact of sociodemographic factors on performance, and incorporate adjustments where needed.**

#### **PROPOSED HOSPITAL ADMISSIONS AND ED VISIT FOR CHEMOTHERAPY MEASURE (OP-35)**

**The AHA does not support the addition of OP-35 to the OQR program unless and until it obtains NQF endorsement. Moreover, we believe CMS must carefully consider the potential for intended consequences in measuring hospital admissions and ED visits of outpatient chemotherapy patients.**

OP-35 calculates two separate rates – inpatient admissions and ED visits – within 30 days for patients receiving chemotherapy treatment in the HOPD setting. Rather than being an “all-cause” measure, OP-35 only includes inpatient admissions and ED visits for the following 10 conditions – anemia, dehydration, diarrhea, emesis, fever, nausea, neutropenia, pain, pneumonia and sepsis. The AHA appreciates CMS’s interest in expanding the number of OQR program measures that address cancer care. We also understand the potential value of data on rehospitalizations for outpatient chemotherapy patients.

However, CMS must carefully weigh the potential value of the measure with the impact it may have on cancer treatment decisions. Cancer patients choose therapies that range from aggressive to palliative. Hospitals work with patients to provide treatments that are best tailored to individual patients’ needs and preferences. However, more aggressive therapies may entail a higher risk of rehospitalization. Given that OP-35 would be publicly reported, it is critically important that the measure not inadvertently discourage more aggressive treatment plans that have clinical benefit and are being pursued in accordance with patients’ preferences.

**If CMS is intent on moving OP-35 forward in the future, it should engage with hospitals, as well as patients and families, to determine what patient populations are the most appropriate to include in the measure.** We appreciate that CMS has chosen to exclude leukemia patients because of concerns that hospital visits for leukemia reflect the relative toxicity of the treatment and frequent recurrence of the disease, rather than shortcomings in quality of care. However, opinions on an appropriate measurement focus are likely to vary, and must be carefully weighed. In general, we believe the measure should focus on populations for whom rehospitalization is most clearly an adverse outcome. For example, the measure could include only patients on palliative treatment regimens, where keeping patients out of the hospital would be a desirable outcome.

**In addition, the AHA is concerned about the validity of using only administrative claims data to capture the measure.** In assessing admissions and ED visits among chemotherapy

patients, CMS assumes that such episodes are caused by how chemotherapy is administered. However, we have heard from hospitals that it is not always clear whether the complications (e.g., nausea, pain) included in the measure are the result of chemotherapy rather than tumor progression. Using claims data alone may not provide sufficient detail to make this important distinction.

#### **PROPOSED HOSPITAL VISITS WITHIN SEVEN DAYS OF OUTPATIENT SURGERY MEASURE (OP-36)**

**The AHA does not support the addition of OP-36 to the OQR program until the measure has been adequately evaluated for the impact of sociodemographic factors on hospital performance. Indeed, this concern applies to all seven of the measures proposed in this rule.** To perform this assessment, CMS could consider using the NQF’s sociodemographic adjustment “trial period.” As part of the trial period, NQF is asking for measure developers to conduct a conceptual and empirical analysis of the impact of sociodemographic status on measure performance when measures are submitted for NQF review.

The evidence continues to mount that sociodemographic factors beyond providers’ control – such as the availability of primary care, physical therapy, easy access to medications and appropriate food, and other supportive services – influence performance on outcome measures. For example, in January 2016, the National Academy of Medicine (NAM) released the first in a planned series of reports that identifies “social risk factors” affecting the health outcomes of Medicare beneficiaries and methods to account for these factors in Medicare payment programs. Through a comprehensive review of available literature, the NAM’s expert panel found evidence that a wide variety of social risk factors may influence performance on certain health care outcome measures, such as readmissions, costs and patient experience of care. These community issues are reflected in readily available proxy data on sociodemographic status, such as U.S. Census-derived data on income and education level, and claims-derived data on the proportion of patients dually eligible for Medicare and Medicaid. The agency also recently adopted a proposal to provide an “interim” adjustment for sociodemographic factors for several measures in the Medicare Advantage Star Rating program. Yet, to date, CMS has resisted calls to incorporate sociodemographic adjustment into the quality measurement programs for hospitals and other providers.

We are concerned that, without sociodemographic adjustment, providers caring for poorer and sicker patients would appear to perform worse on some outcome measures than others treating a different patient population. Indeed, measures that fail to adjust for sociodemographic factors when there is a conceptual and empirical relationship between those factors and the measure outcome lack credibility, unfairly portray the performance of providers caring for more complex and challenging patient populations, and may serve to exacerbate health care disparities.

#### **PROPOSED OAS CAHPS SURVEY MEASURES (OP-37A-E)**

**The AHA has long been supportive of rigorously-designed surveys of patient experience of care, including the Hospital Consumer Assessment of Healthcare Providers and Systems**

**(HCAHPS) survey. However, we believe the implementation of OAS CAHPS is premature for a number of reasons.** First, the OAS CAHPS survey measures are not endorsed by the NQF, which significantly limits all stakeholders' insight into whether the measures portray hospital performance in a fair and accurate manner. Given the significant resources needed to collect survey data, we believe the measures should be NQF endorsed before OAS CAHPS is required of hospitals.

**Additionally, we are concerned that the CAHPS program already includes multiple, and potentially overlapping, survey tools. A requirement to collect yet another CAHPS survey may lead to confusion among patients about which provider is being assessed and excessive survey administration burden.** A patient's course of care often crosses multiple care settings and providers within a given time period, and the CAHPS program has surveys for nearly every setting. Indeed, CAHPS includes surveys for physicians, hospitals, nursing homes, dialysis facilities and home health agencies. In addition, we understand that a survey for hospital EDs is under development. Patients who receive care in two or more of these settings could receive multiple surveys. Typically, surveys are not distributed until days or weeks after a patient has received his or her care. This may create confusion about which provider or facility is actually being assessed. A patient may inadvertently attribute a positive or negative experience to the wrong provider.

**Correct attribution of performance results could be especially problematic if a new survey for ASCs and HOPDs is implemented because two existing CAHPS surveys – the Clinician/Group CAHPS (CG-CAHPS) and the Surgical CAHPS – capture closely related information.** In the proposed rule, CMS suggests that OAS CAHPS is needed in order to capture the performance of HOPDs and ASCs, rather than that of individual physicians. However, we believe the content of both CG-CAHPS and Surgical CAHPS already include information highly relevant to assessing experience of care in ASCs and HOPDs. The CG-CAHPS survey evaluates practices and individual providers on several issues, including access to appointments, physician communication with patients, courtesy of office staff and follow up on testing results. The Surgical CAHPS survey captures similar information, but with a focus on surgical care in both the inpatient and outpatient settings. Patients rate the quality of pre-and-post procedure information provided to them, the helpfulness of office staff, and communication with surgeons and anesthesiologists before and after the procedure. If CMS implements yet another survey relevant to outpatient surgical patients, then patients may receive three separate but similar surveys for exactly the same care episode.

**At a minimum, we urge CMS to carefully examine its CAHPS survey requirements across all of its reporting programs to minimize the number of surveys that patients must respond to during a given timeframe.** We also urge CMS to ensure survey administration protocols clearly identify which particular institution is being surveyed to help ensure correct attribution of experiences. The AHA would be pleased to work with the agency, as well as with patients and other stakeholders, on this effort.

**Lastly, we strongly urge CMS to explore the development of more economical survey administration approaches for the OAS CAHPS and all other CAHPS surveys, such as**

**emailed or web-based surveys.** While we appreciate the value of assessing the patient experience across the care continuum, the use of multiple surveys means more time spent by patients to answer surveys, and more resources expended by providers to administer them. Moreover, for the purposes of CMS reporting programs using CAHPS tools, providers are permitted to use only two survey administration modes – mailed surveys and telephone surveys. Mailed surveys are relatively inexpensive to administer, but often suffer from low response rates and a significant time lag. Telephonic surveys typically yield a higher response rate and provide more timely results, but are much more expensive to administer.

We strongly encourage CMS to work with the CAHPS Consortium to develop guidelines for emailed and web-based surveys for the entire CAHPS family. Once this guidance is developed, CMS should permit the use of emailed and web-based surveys in CMS reporting programs. To date, the Agency for Healthcare Research & Quality (AHRQ) has provided very limited guidance on appropriate procedures for using electronic survey methodologies. Yet, electronic survey administration modes, such as email and web-based portals, make survey data collection and aggregation timelier and less expensive, and may allow hospitals to increase sample size without greatly increasing cost. In developing guidance for emailed and web-based surveys, AHRQ also should engage with hospitals and other providers that have been using emailed and web-based surveys to collect data on patient experience informally.

## **PROPOSED CHANGES TO THE MEDICARE AND MEDICAID ELECTRONIC HEALTH RECORD (EHR) INCENTIVE PROGRAM**

CMS proposes several changes to the Medicare and Medicaid EHR Incentive Program for Modified Stage 2 and Stage 3 including changing the EHR reporting period in CY 2016 for eligible hospitals (EHs), CAHs and eligible professionals (EPs); changing the EHR Incentive Program objectives and measures for EHs and CAHs for Modified Stage 2 and Stage 3; and revising the reporting period for EHs, CAHs and EPs that are new program participants in CY 2017. Our comments on these proposals follow, while Appendix B provides detailed comments on the proposed changes to the Stage 3 objectives and measures. We also recommend revisions to the EHR Incentive Program framework and program requirements to improve the prospects for program success.

### **COMMENTS ON SPECIFIC PROPOSALS**

Proposed Reporting Period for 2016. CMS proposes to reduce the Modified Stage 2 reporting period in 2016 from a full calendar year to any 90 consecutive days. **The AHA appreciates the proposed 90-day reporting period for 2016 and urges CMS to finalize this proposal.**

Proposed Changes to Modified Stage 2 and Stage 3. For Modified Stage 2 in CY 2017 and for Stage 3, CMS proposes to remove the Clinical Decision Support (CDS) and Computerized Provider Order Entry (CPOE) objectives and associated measures. **The AHA supports the**

**proposal to reduce the number of objectives and associated measures from the EHR Incentive Program and recommends that the change be finalized as proposed.**

CMS proposes to reduce the measure for the Modified Stage 2 Patient Electronic Access objective to at least one unique patient (or patient-authorized representative) discharged from the EH or CAH inpatient or ED (POS 21 or 23) views, downloads or transmits to a third party his or her health information during the EHR reporting period. **The AHA appreciates the proposed change and strongly urges CMS to finalize the revised measure as proposed.**

CMS proposes to reduce the public health and clinical data registry reporting requirement by requiring that EHs and CAHs report to three of the registries or report an exclusion. **The AHA supports the proposal to reduce the public health reporting requirements for Stage 3.**

CMS proposes to reduce seven measure thresholds associated with three Stage 3 objectives. The AHA appreciates the consideration CMS gave to the comments submitted in response to the October 2015 *Electronic Health Record Incentive Program – Stage 3 and Modifications to Meaningful Use in 2015 through 2017 Final Rule with Comment Period*. We appreciate the proposals to reduce the measure thresholds, but we continue to have specific concerns about the measure requirements, including the required use of functionality that is not mature. Please see Appendix B for our specific concerns and recommendations.

CMS proposes to apply any changes to program requirements for Stage 3 only to Medicare and not to Medicaid. **The AHA recommends that CMS apply the finalized changes to EHs and CAHs participating in the Medicaid EHR Incentive Program.** We believe that it is important to retain the same objectives, measures and thresholds for measures in both programs to avoid adding to the program's complexity. As a rationale for separate requirements, CMS expressed concern about the ability of the states to modify their receiving systems on a short timeframe. To address this concern, we recommend applying a 90 day reporting period for 2017 and subsequent years, so that states have additional time to prepare for the changes to the program requirements. We also urge CMS to assess whether the agency can receive the attestations from Medicaid EHR Incentive Program-only participants on behalf of the states in order to support the alignment of the meaningful use requirements in both programs.

Proposed Program Changes for 2017 Reporting. CMS proposes that EHs, CAHs and EPs new to the EHR Incentive Program in 2017 may only attest to Modified Stage 2 and do so by Oct. 1, 2017. CMS states that CMS system issues will not support the option for new program participants to attest to Stage 3. CMS notes that a new EHR Incentive Program reporting platform will be utilized by program participants in 2017, coinciding with new reporting requirements for EPs participating in Medicare Access and Chip Reauthorization Act (MACRA) programs. **The AHA recommends that CMS provide specific information about new reporting platforms in the final rule so that EHs and CAHs will have time to prepare for registration and attestation requirements that may be new, additional or revised from current requirements.**

## **RECOMMENDATIONS TO REVISE THE EHR INCENTIVE FRAMEWORK AND INCREASE PROGRAM SUCCESS**

In addition to the flexibilities proposed, **the AHA recommends that CMS revise the framework of the Medicare and Medicaid EHR Incentive Program and further modify program requirements to increase flexibility that will support provider success.** Our specific recommendations follow:

Allow a Permanent Reporting Period of any 90 Consecutive Days for Meaningful Use Beginning in 2017. **The AHA recommends a reporting period of any 90 days for the 2017 reporting period and subsequent years.** Experience to date indicates that transitions to new program requirements or new editions of certified EHRs are challenging due to lack of vendor readiness, the necessity to update other systems to support the new data requirements, mandates to use immature standards, an insufficient information exchange infrastructure and timelines that are too compressed to support successful change management. A 90-day reporting period would give providers time to meet these challenges in a safe and orderly manner. A 90-day reporting period also would give the states time to prepare their systems to accommodate changes in program requirements.

Postpone the Required Start of Stage 3 Until a Date No Sooner than 2019. **The AHA recommends that CMS refrain from requiring Stage 3 in 2018 and finalize a Stage 3 start no sooner than 2019.** The EHR development and certification cycle to date has required a minimum of 18 months from the time of the release of new meaningful use rules to the widespread availability of certified EHRs. Once hospitals receive the updated EHR software, the experience to date indicates that up to an additional 19 months is required to safely and successfully implement the new technology. This process includes time for software assessment; installation, implementation and training for staff that will use the systems; time to build up to the performance metrics required by meaningful use; and time to capture actual data in a reporting period. As of August 2016, 17 months before the start of 2018, eight products are listed in the Office of National Coordinator certified EHR product list (ONC CHPL) as certified to 2015 edition EHR certification criteria, but none of the eight are certified for the inpatient setting. It is unlikely that all hospitals will have newly certified and implemented EHRs and be ready to begin a full-year reporting period starting Jan. 1, 2018. Rather, it is more likely that the past experience – vendor delays and the prospect of penalties for providers, despite their best efforts at complying with the regulatory requirements – would be repeated. All providers require sufficient time to implement and upgrade technology and optimize performance before moving to more complex requirements for use.

Eliminate the All-or-Nothing Approach in Meaningful Use. Section 1886(n)(3) of the Social Security Act states that an EH or CAH shall be treated as a meaningful EHR user for an EHR reporting period if three requirements are met:

- Demonstrates to the satisfaction of the Secretary that during the reporting period, the use of certified EHR technology in a meaningful manner;

- The certified EHR technology is connected in a manner that provides for the electronic exchange of health information to improve the quality of health care, such as promoting care coordination; and
- Submits information in a form and manner specified by the Secretary on clinical quality measures and such other measures as selected by the Secretary.

Congress gave CMS exceedingly broad discretion to determine whether a hospital is a meaningful EHR user. The inclusion in the program of more stringent measures over time does not require an all-or-nothing approach to meet program requirements. The statute states that CMS “shall seek to improve the use of electronic health records and health care quality over time by requiring more stringent measures of meaningful use selected under this paragraph.” However, this language is not part of the definition of meaningful EHR user. **The AHA recommends CMS adopt an alternate approach to all-or-nothing that advances widespread health IT adoption and use by all EHRs and CAHs with requirements that are practical and achievable. Specifically, the AHA recommends that EHRs and CAHs that attest to meeting 70 percent of the meaningful use measures be designated as meaningful users of certified EHRs.** We believe the level of difficulty associated with meeting all of the current measures is overly burdensome. Some of the measures require the use of certified EHRs in a manner that is not supported by mature standards, technology functionality or an available infrastructure.

Align Program Requirements with the Requirements on Eligible Professionals Under MACRA.

The MACRA proposed rule includes changes to the EHR Incentive Program that revise the reporting requirements for eligible clinicians. The Advancing Care Information (ACI) category in the MACRA proposed rule would assess participants according to a base score and a performance score. The performance score includes objectives and measures that a clinician may, but not be required, to report. The AHA agrees with this approach as the base score focuses on the availability of EHR functionality for clinician use and moves away from counting the number of times a clinician uses certified EHRs in the delivery of care. We also believe the composite score can be set at a level that supports our recommendation that achieving 70 percent of the measures attains successful meaningful use of certified EHRs. **The AHA recommends that revisions in the structure and requirement of the EHR Incentive Program for EHRs and CAHs are aligned with the structure and requirements that would be finalized in the ACI performance category in the MACRA proposed rule.** This will support the exchange of health information in support of care coordination across the continuum.

In the OPPS proposed rule, CMS seeks comment on how measures of meaningful use under the EHR Incentive Program can be made more stringent in future years; the proposed thresholds or whether different thresholds would be more appropriate; and new and more stringent measures for future years of the EHR Incentive Program. **To inform future policymaking, the AHA recommends that CMS arrange for a third-party evaluation of the hospital experience in Modified Stage 2. Additionally, CMS should work with ONC and other federal partners**



**and the private sector to accelerate the availability of mature standards and the infrastructure needed for efficient and effective health information exchange.**

Provide a Hardship Exemption from Meaningful Use Penalties for any EH, CAH or EP that Changes Vendors During a Reporting Period. The expense of adopting, implementing and upgrading technology are ongoing, while the program demands certified EHRs support information exchange for a full performance period. As referenced earlier, we have concerns about the number of certified EHR solutions available to support providers. **The AHA recommends expanding the hardship exception categories to allow providers to change EHR vendors during a reporting period to meet their needs without the additional burden of a payment adjustment.**

Adopt Program Requirements Supported by Mature Interoperability Standards and Infrastructure. Mature standards must exist before providers are required by regulation to use them. The transition to new technology supporting Stage 2 has been a challenge for providers due to lack of vendor readiness, mandates to use untested standards, insufficient infrastructure to meet requirements to share information and compressed timelines. **The AHA recommends that CMS refrain from including requirements in regulation that providers use a standard or functionality in certified EHRs in advance of evidence that the standard or functionality is ready for nationwide use.**

For example, it is premature to require that providers use Application Programming Interfaces (APIs) in the EHR to make health information accessible by any application (app) that requests to access to the information. Although ONC finalized three certification criteria in support of APIs in the 2015 Edition Certification Rule, ONC specifically did not recognize a standard for APIs, citing standards immaturity. Additionally, ONC finalized the API requirements without specifying a certification approach or framework applicable to the apps that would extract data from the EHR.

Furthermore, the requirement to connect with any app of the patient's choice poses significant security concerns for hospitals. Given the alarming trend in cyber attacks in health care, providers must be granted the right to control the technology that is connected to their systems in order to keep them secure. Furthermore, the majority of patient-facing apps are not covered by the HIPAA privacy and security requirements governing health care providers. Therefore, consumers may be surprised when the marketers of health apps share their sensitive health information obtained from providers in ways that are not allowed by HIPAA. Recent studies have shown that the majority of health apps on the market today do not have adequate privacy policies and routinely share sensitive health information with third parties (see, for example, Privacy Policies of Android Diabetes Apps and Sharing of Health Information, JAMA, March 8, 2016, available at <http://jama.jamanetwork.com/article.aspx?articleid=2499265>). **Therefore, the AHA recommends that CMS remove the API requirement from the patient access measure.**

Robust Testing and Implementation Guidance of Mature Standards Must Precede Requirements for Provider Use. The experience using the consolidated clinical data architecture (C-CDA)

standard to exchange summary of care records illustrates the problems with using standards that have not been adequately specified. Hospitals that receive summary of care documents find they are too large, and it is difficult to find what is relevant and pertinent. For example, for patients that require hospitalization: the patient record is managed by a provider who will send a summary of care record to the hospital; the hospital will send a summary of care record back to the provider upon discharge; and the provider will receive a record with all laboratory results, imaging results and medications from the current and prior stays – a large amount of information that is unlikely to indicate the most pertinent information that will support ongoing management of the patient. This challenge has been acknowledged by providers, vendors and the government. The creator of the C-CDA standard, HL7, is working to improve the C-CDA to make it more flexible so that all information can be exchanged and relevant information can be presented in an accessible manner, but that work is ongoing and has not been tested in real-world settings. **Therefore, while the AHA appreciates the reduction in the threshold for sharing summary of care documents to 10 percent in Stage 3, we also recommend that CMS work with other agencies to improve the usefulness of the C-CDA standard and remove requirements on the information shared so that clinicians can use their clinical judgment to share the information they believe is most important for the next provider of care.**

While the demand for information exchange grows, **the AHA urges CMS to work with federal agencies to prioritize the development of a patient identifier.** Providers are experiencing challenges in identifying patients and matching them to their medical records. The nation lacks a single national mechanism for identifying individuals such as a unique patient identifier. A single solution that would match individuals across IT systems would allow providers to know with confidence that a patient being treated in an emergency department is the same patient that a physician in another location diagnosed with an acute or chronic health condition that requires ongoing management. Patient safety concerns arise when data are incorrectly matched, such as a patient's current medication not being listed in the medical record or the wrong medications are included in the record. Stage 3 includes a measure requiring a clinical information reconciliation that includes medications, medication allergy and current problem list for more than 80 percent of transitions or referrals in which the provider has never before encountered the patient. This requirement would be easier to achieve with advancement of a patient matching solution.

## **REMOVAL OF HCAHPS PAIN QUESTIONS FROM VBP SCORES**

**The AHA supports CMS's proposal to exclude the results from three pain-management questions in the HCAHPS survey in determining hospitals' value-based payment (VBP) program scores.** We have urged the agency to suspend the current pain-related questions in the VBP program to address concerns that they may create pressure to prescribe opioids. As the country struggles with a devastating opioid epidemic, we agree that CMS should explore new ways to ask patients about how well the hospital staff addressed their pain. The AHA believes that CMS should continue to collect and publicly report the results of the current HCAHPS pain-management questions in the interim. We urge the agency to work quickly to propose new

questions assessing pain management in next year's rulemaking cycle and welcome the opportunity to assist CMS in that effort.

## **PROPOSED CHANGES TO THE MEDICARE REQUIREMENTS FOR TRANSPLANT CENTERS AND ORGAN PROCUREMENT ORGANIZATIONS**

### **PROPOSED CHANGES TO THE CONDITIONS OF PARTICIPATION FOR TRANSPLANT PROGRAMS**

**The AHA supports the following proposed changes to the Conditions of Participation (CoPs) for solid organ transplant programs:**

- Observed to Expected Rates. Among the outcome requirements described in the CoPs currently, a transplant program will be noncompliant with patient and graft survival standards if it crosses three specific thresholds: (1) the observed to expected (O/E) ratio of patient deaths and graft failures exceeds 1.5; (2) the results are statistically significant ( $p < .05$ ); and (3) the results are numerically meaningful (if the number of observed events minus the expected number surpasses 3). **We agree with CMS's proposal to change the first threshold from 1.5 to 1.85 for all organ types.** The agency hopes that, by "restoring rough parity to 2007 graft failure rates," transplant centers will be encouraged "to use more of the increasing number of viable organs."
- Mitigating Factors Review: Timeframes for Notification/Data Submission. The CoPs allow CMS to consider select "mitigating factors" in some circumstances when approving or reapproving a transplant center. We support CMS's proposal to extend and clarify the timeframes for transplant centers to notify the agency of the intent to request a mitigating factors approval and submit the relevant data for review. Specifically, we agree that CMS should extend the notification period from 10 days to 14 calendar days and clarify that the timeframe to submit mitigating factors materials is 120 calendar days.

### **ORGAN PROCUREMENT ORGANIZATIONS (OPO)**

The AHA supports CMS's proposal to reduce the amount of paper documentation that must be sent to a receiving transplant center, as the agency states that the data can be accessed electronically.

### Appendix A: Current Measures Proposed for Retention Aligned by AHA Quality Measurement Priority Area

AHA Measurement Priority Areas	Measures Kept (Possible Minor Modifications)	Measures Kept If Major Modifications Made
<p><b>Patient Safety Outcomes</b></p> <ul style="list-style-type: none"> <li>• <b>Harm Rates</b></li> <li>• <b>Infection Rates</b></li> <li>• <b>Medication Errors</b></li> </ul>	<p>Central-line associated bloodstream infection (CLABSI)</p> <p>Surgical site infection (colon and hysterectomy procedures only)</p> <p>Catheter-associated urinary tract infection (CAUTI)</p> <p><i>Clostridium Difficile</i> (C Difficile)</p> <p>Methicillin Resistant Staphylococcus Aureus (MRSA)</p> <p>Global influenza vaccination</p> <p>Influenza vaccination coverage among health care personnel (inpatient)</p> <p>OP-27: Influenza vaccination coverage among health care personnel (outpatient)</p>	<p>Risk-standardized complication rate following elective primary total hip and/or total knee arthroplasty</p> <p>Severe sepsis and septic shock management bundle</p>
<p><b>Readmission Rates</b></p> <p><b>Effective Patient Transitions</b></p>		<p>Acute myocardial infarction (AMI) 30-day risk standardized readmission</p> <p>Heart failure (HF) 30-day risk standardized readmission</p> <p>Pneumonia (PN) 30-day risk standardized readmission</p> <p>Total Hip / Total Knee Arthroplasty (THA/TKA) 30-day risk standardized readmission</p> <p>COPD 30-day risk standardized readmission</p>

AHA Measurement Priority Areas	Measures Kept (Possible Minor Modifications)	Measures Kept If Major Modifications Made
		Coronary artery bypass graft (CABG) 30-day risk standardized readmission  Acute ischemic stroke (STK) 30-day risk standardized readmission  Hospital-wide all cause unplanned readmission  OP-32: Facility 7-day risk-standardized hospital visit rate after outpatient colonoscopy
<b>Risk Adjusted Mortality</b>		AMI 30-day mortality rate  HF 30-day mortality rate  PN 30-day mortality rate  CABG 30-day mortality  AMI 30-day risk standardized readmission
<b>Diabetes Control</b>	NO MEASURES AVAILABLE IN HOSPITAL PROGRAMS	
<b>Obesity</b>	NO MEASURES AVAILABLE IN HOSPITAL PROGRAMS	
<b>Adherence to Guidelines for Commonly Overused Procedures</b>		OP-33: External beam radiotherapy (EBRT) for bone metastases  OP-29: Endoscopy/Poly Surveillance: Appropriate follow-up interval for normal colonoscopy in average risk patients  OP-30: Endoscopy/Poly Surveillance: Colonoscopy interval for patients with a history of adenomatous polyps—Avoidance of inappropriate use

AHA Measurement Priority Areas	Measures Kept (Possible Minor Modifications)	Measures Kept If Major Modifications Made
		OP-8: MRI lumbar spine for low back pain  OP-11: Thorax CT – Use of contrast material  OP-13: Cardiac imaging for preoperative risk assessment for non-cardiac low-risk surgery
<b>End-of-Life Preferences</b>	NO MEASURES AVAILABLE IN HOSPITAL PROGRAMS	
<b>Cost Per Case or Episode</b>		Medicare spending per beneficiary (MSPB)
<b>Behavioral Health</b>	NO MEASURES AVAILABLE IN HOSPITAL PROGRAMS	
<b>Patient Experience of Care/ Patient Reported Outcomes of Care</b>		HCAHPS survey

## Appendix B: AHA Comments on Proposed Changes to the EHR Incentive Program Stage 3 Final Requirements

Final Rule Stage 3 Objective	Final Rule Stage 3 Measures	Proposed Stage 3 Objectives and Measures In CY 2017 Hospital OPps NPRM	AHA Comment on Proposed Stage 3 Objectives and Measure in CY 2017 Hospital OPps NPRM
Protect electronic health information (ePHI): Protect ePHI created or maintained by the certified electronic health record technology (certified EHR) through the implementation of appropriate technical, administrative and physical safeguards.	Conduct or review a security risk analysis per Health Information Portability and Accountability Act (HIPAA), including assessing the security (including encryption) of data created or maintained by certified EHR in accordance with requirements under 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), implement security updates as necessary, and correct identified security deficiencies as part of the EH's or CAH's risk management process.	No change to objective or measure.	The AHA supports maintaining the previously finalized Stage 2 objective and the stability in the measure for Stage 3.
Electronic prescribing: Eligible hospitals (EHs) and CAHs must generate and transmit permissible discharge prescriptions electronically (eRx).	More than 25 percent of EH or CAH discharge medication orders for permissible prescriptions (new and changed) are queried for a drug formulary and transmitted electronically using certified EHR.	No change to objective or measure.	The AHA opposes the 25 percent threshold for this measure and recommends a threshold that is no more than 10 percent. The AHA recommends that CMS offer in 2017 the availability of an exclusion for EHs and CAHs that has not selected the e-prescribing objective as an optional program requirement in 2014.
Clinical decision support (CDS): Implement CDS interventions focused on improving performance on high-priority health conditions.	<p>Measure 1. Implement five CDS interventions related to four or more clinical quality measures (CQMs) at a relevant point in patient care for the entire EHR reporting period.</p> <p>Measure 2. Enable and implement the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period.</p>	Proposed removal of the objective and measure	The AHA supports the removal of the CDS objective and associated measure.
Computerized Provider Order Entry (CPOE): Use CPOE for medication, laboratory and diagnostic imaging orders.	Measure 1. CPOE for medication - More than 60 percent of medication orders created by authorized providers of the EH or CAH inpatient or ED (POS 21 or	Proposed removal of the objective and measure	The AHA supports the removal of the CPOE objective and associated measures.

Final Rule Stage 3 Objective	Final Rule Stage 3 Measures	Proposed Stage 3 Objectives and Measures In CY 2017 Hospital OPPS NPRM	AHA Comment on Proposed Stage 3 Objectives and Measure in CY 2017 Hospital OPPS NPRM
	<p>23) during the EHR reporting period are recorded using CPOE.</p> <p>Measure 2. CPOE for labs - More than 60 percent of laboratory orders created by the authorized providers of the EH or CAH inpatient or ED (POS 21 or 23) during the EHR reporting period are recorded using CPOE.</p> <p>Measure 3. CPOE for diagnostic imaging – More than 60 percent of diagnostic imaging orders created by the authorized providers of the EH or CAH inpatient or ED (POS 21 or 23) during the EHR reporting period are recorded using CPOE.</p>		
<p>Patient electronic access to health information: Use the certified EHR functionality to provide patient access health information or patient-specific educational resources.</p>	<p>Measure 1. For more than 80 percent of unique patients, either: (i) the patient (or patient-authorized representative) is provided timely access to view online, download, and transmit their health information - and (ii) the provider ensures the patient’s health information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the API in the provider’s certified EHR.</p> <p>Measure 2. Use certified EHR to identify patient-specific educational resources and provide electronic access to those materials to more than 35 percent of unique patients.</p>	<p>Measure 1. For more than 50 percent of unique patients, either: (i) the patient (or patient-authorized representative) is provided timely access to view online, download, and transmit their health information - and (ii) the provider ensures the patient’s health information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the API in the provider’s certified EHR.</p> <p>Measure 2. Use certified EHR to identify patient-specific educational resources and provide electronic access to those materials to more than 10 percent of unique patients.</p>	<p>The AHA opposes the requirement to use API functionality for patient engagement for educational resources or for health information exchange through patient engagement in advance of a mature standard and certification of patient-selected applications.</p> <p>The AHA opposes the requirement to make any patient health information available within 36 hours of its availability to the provider for an eligible hospital or CAH by means of view, download, transmit and through an API of the patient’s choice as it would present operational challenges to hospitals.</p> <p>Measure 2. Given the current lack of patient demand for or benefit from electronic access to educational resources, the AHA opposes the use of a specific threshold for this measures. We recommend a measure of the availability of the functionality in the EHR (yes/no). A study and</p>



Final Rule Stage 3 Objective	Final Rule Stage 3 Measures	Proposed Stage 3 Objectives and Measures In CY 2017 Hospital OPPTS NPRM	AHA Comment on Proposed Stage 3 Objectives and Measure in CY 2017 Hospital OPPTS NPRM
			evaluation of patient preferences and provider experience with use and optimization of the functionality will inform future requirements including the necessity of a measure threshold.
<p>Coordination of Care through Patient Engagement: Use certified EHR functionality to engage with patients or their authorized representatives. EH and CAH must attest/report the numerators/denominators for all three measures and must meet thresholds for two out of three measures.</p>	<p>Measure 1. More than 10 percent of all unique patients (or their authorized representatives) discharged from the eligible hospital or CAH inpatient or ED (POS 21 or 23) actively engage with the EHR made accessible by the provider. Measure to be met by patient is one of the following (i) view, download, or transmit to a third party their health information, (ii) access their health information through the use of an API that can be used by applications chosen by the patient and configured to the API in the provider's certified a combination of (i) and (ii).</p> <p>Measure 2. For more than 25 percent of all unique patients or patient's authorized representative discharged from EH or CAH inpatient or ED (POS 21 or 23), certified EHR was used to send a secure message to the patient or used in response to a secure message sent by the patient.</p> <p>Measure 3. Patient generated data or data from a non-clinical setting is incorporated into the certified EHR for more than 5 percent of all unique patients.</p>	<p>Measure 1. For at least one unique patient (or their authorized representatives) discharged from the EH or CAH inpatient or ED (POS 21 or 23) actively engage with the electronic health record made accessible by the provider. Measure to be met by patient is one of the following (i) view, download, or transmit to a third party their health information, (ii) access their health information through the use of an API that can be used by applications chosen by the patient and configured to the API in the provider's certified a combination of (i) and (ii).</p> <p>Measure 2. For more than five percent of all unique patients or patient's authorized representative discharged from EH or CAH inpatient or ED (POS 21 or 23), certified EHR was used to send a secure message to the patient or used in response to a secure message sent by the patient.</p> <p>Measure 3. Patient generated data or data from a non-clinical setting is incorporated into the certified EHR for more than 5 percent of all unique patients.</p>	<p>Measure 1. The AHA opposes the requirement to use API functionality for patient engagement with a EH's or CAH's EHR in advance of a mature standard and certification of patient- selected applications. The AHA strongly supports changing the threshold to at least one patient.</p> <p>A study and evaluation of patient and provider experience with use and optimization of the functionality will inform future requirements including the necessity of a measure threshold.</p> <p>Measure 2: The AHA recommends that the secure message measure should be applicable <b>only</b> to EPs as a patient following an acute care visit is more likely to access information through a primary care provider than from the hospital directly. If CMS finalizes this measure for hospitals, we recommend that the threshold be at least one patient in order to focus on the availability of secure messaging to send or receive a patient's secure message.</p> <p>Measure 3. The AHA believes it is premature to include a measure that requires provider use of certified EHR functionality to support receipt of patient-generated data or data from non-clinical settings. The AHA recommends that CMS either</p>

Final Rule Stage 3 Objective	Final Rule Stage 3 Measures	Proposed Stage 3 Objectives and Measures In CY 2017 Hospital OPps NPRM	AHA Comment on Proposed Stage 3 Objectives and Measure in CY 2017 Hospital OPps NPRM
			remove this measure or reduce the threshold to at least one patient.
<p>Health information exchange: provide a summary of care record when transitioning or referring their patient to another setting of care, or retrieve a summary of care record upon the first patient encounter with a new patient. EH/CAH must attest/report the numerators/denominators for all three measures. Must meet threshold on two of three measures.</p>	<p>Measure 1. For more than 50 percent of transitions of care and referrals, a summary of care record is created and sent electronically.</p> <p>Measure 2. For more than 40 percent of transitions and referrals received and patient encounters in which the provider has never before encountered the patient, incorporate into the patient's EHR an electronic summary of care document from a source other than the provider's EHR system.</p> <p>3. For more than 80 percent of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the EH, CAH or EP performs a clinical information reconciliation that includes medications, medication allergy and current problem list.</p>	<p>Measure 1. For more than 10 percent of transitions of care and referrals, a summary of care record is created and sent electronically.</p> <p>Measure 2. For more than 10 percent of transitions and referrals received and patient encounters in which the provider has never before encountered the patient, incorporate into the patient's EHR an electronic summary of care document from a source other than the provider's EHR system.</p> <p>3. For more than 50 percent of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the EH, CAH or EP performs a clinical information reconciliation that includes medications, medication allergy and current problem list.</p>	<p>Measure 1: The AHA appreciates the flexibility proposed and urges CMS to finalize the threshold that EHs and CAHs use their certified EHR to create and electronically send a summary of care for more than 10 percent of transitions of for summary of care.</p> <p>Measure 2: The AHA also recommends that CMS further reduce the threshold to at least one patient transferred or referral received in which the provider has never before encountered the patient, incorporate into the patient's EHR an electronic summary of care document from a source other than the provider's EHR system. Experience to date indicates ongoing challenges with receipt of the electronic summary of care from clinical settings transferring or referring a patient to the EH or CAH. AHA urges CMS to accelerate efforts to improve the information exchange infrastructure and to support other providers in increasing their capability of participating in information exchange.</p> <p>Measure 3: The AHA supports retaining the medication reconciliation measure for Stage 3, rather than requiring the clinical information reconciliation measure.</p> <p>Should CMS finalize the clinical reconciliation measure, the AHA strongly opposes the 50 percent threshold for the clinical information reconciliation for Stage 3. This requirement precedes the readiness of patient</p>

Final Rule Stage 3 Objective	Final Rule Stage 3 Measures	Proposed Stage 3 Objectives and Measures In CY 2017 Hospital OPPTS NPRM	AHA Comment on Proposed Stage 3 Objectives and Measure in CY 2017 Hospital OPPTS NPRM
			<p>matching solutions and the availability of EHR interoperability that supports the exchange and use of accurate health information within a recipient’s EHR without manual effort. This measure is new in Stage 3, and precedes any experience in the field with technology capable of supporting this level of clinical information reconciliation.</p>
<p>Public health and clinical data registry reporting: EH or CAH is in active engagement with a public health agency (PHA) or clinical data repository (CDR) to submit electronic public health data in a meaningful way using certified EHR, except where prohibited and in accordance with applicable law. EHs and CAHs must attest/report on four measures. The registry measures may be counted more than once if multiple registries are supported.</p>	<p>Measure 1. Immunization registry reporting. The EH or CAH is in active engagement with a PHA to submit immunization data and receive immunization forecasts and histories from the public health immunization registry/immunization information system (IIS).</p> <p>Measure 2. Syndromic surveillance reporting. The EH or CAH is in active engagement with a public health agency to submit syndromic surveillance data from an urgent care setting.</p> <p>Measure 3. Case reporting. The EH or CAH is in active engagement with a public health agency to submit case reporting of reportable conditions.</p> <p>Measure 4. Public health registry reporting. The EH or CAH is in active engagement with a public health agency to submit data to public health registries.</p> <p>Measure 5. Clinical data registry reporting. The EH or CAH is in active engagement to submit data to a clinical data registry.</p> <p>Measure 6. Electronic reportable lab results. The EH or CAH is in</p>		<p>The AHA appreciates the proposed requirement to report on three measures rather than four measures to reduce the reporting burden on hospitals.</p> <p>AHA urges CMS to develop a publically available website that lists clinical registries available to support the active engagement requirement.</p> <p>AHA also recommends that CMS clarify the definition of clinical data registry that meets the requirements for provider participation in support of the measure requirements.</p> <p>Measure 1. Immunization registries across the country are in different stages of development with respect to bi-directional exchange of information. Therefore, we recommend CMS clarify in the final rule that a provider also can meet this measure by being in active engagement with a PHA to submit immunization data, in the event that the PHA cannot send immunization forecasts or other information to the provider.</p>

<b>Final Rule Stage 3 Objective</b>	<b>Final Rule Stage 3 Measures</b>	<b>Proposed Stage 3 Objectives and Measures In CY 2017 Hospital OPSS NPRM</b>	<b>AHA Comment on Proposed Stage 3 Objectives and Measure in CY 2017 Hospital OPSS NPRM</b>
	active engagement with a public health agency to submit electronic reportable laboratory results.		

To: American Hospital Association (AHA)  
Federation of American Hospitals (FAH)  
Association of American Medical Colleges (AAMC)

From: Watson Policy Analysis (WPA)

Date: August 16, 2016

Subject: Impact of change in unrelated lab packaging

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### *Summary*

In the CY2017 proposed Outpatient Prospective Payment System (OPPS) rule, the Centers for Medicare & Medicaid Services (CMS) proposes to discontinue use of the L1 modifier on claims to identify unrelated laboratory tests and instead package all laboratory tests. CMS estimates that this policy change will have a 0.03% impact on payment. However, in our analyses, we estimate that there will be a greater impact -- assuming that payment impacts correlate with cost -- instead in the range of 0.06% to 0.09%.

### *CMS Proposal*

In the rule, CMS lays out several reasons why they believe that all laboratory costs should be packaged. This memo is not going to address the appropriateness of those policies but will instead focus solely on the impact of those policies.

On P. 45628 of the Federal Register version of the proposed rule (Volume 81, Number 135, July 14, 2016), following a discussion of their logic, CMS writes: "Instead, we are proposing to package any and all laboratory tests if they appear on a claim with other hospital outpatient services. We are inviting public comments on this proposal."

In terms of the impact overall payments, CMS writes on P. 45764 of the Federal Register version of the proposed rule that they anticipate an additional "...0.03 percent to account for our proposal to package unrelated laboratory tests into OPPS payment".

CMS writes on P. 45610 of the Federal Register version of the rule that they estimate proposed total payments to OPPS providers for CY2017 to be "approximately \$63 billion". Our calculation taking 0.03 percent of \$63 billion is approximately \$19 million.

Using the facility specific impact file released with the rule, the total estimated OPPS payment (including outliers) is estimated to be approximately \$50 billion. Our calculation taking 0.03 percent of \$50 billion is approximately \$15 million.

Based on these calculations using published CMS factors, we estimate a range of approximately \$15 to \$19 million for the estimated adjustment to OPPS payments by CMS.

## *Analysis*

To test this calculation to see if that range is appropriate, we estimated the amount of cost associated with unrelated laboratory lines on outpatient claims with a payable procedure. Our methodology is summarized as follows:

- 1) Using the OPSS rate-setting data for CY2017 (containing 2015 claims), restrict the data to billtype 13X – outpatient claims.
- 2) With the data from the previous step, identify all laboratory procedures (Q4 status indicator) with an L1 modifier indicating that it is an unrelated laboratory test.
- 3) Examine the claims containing the laboratory tests in the previous step, and identify if there was a separately payable procedure on the claim. Separately payable OPSS procedure identified by having status indicator: S, T, V, J1, J2, Q1, Q2, or Q3. This list of separately payable codes is consistent with the CY2016 Final Rule Claims Accounting in the description of how to handle laboratory tests with a Q4 status indicator.
- 4) Compute the total cost for the lines which met all of the following criteria:
  - a. On Billtype 13X
  - b. Have an L1 modifier
  - c. On a claim with a payable OPSS code

With this proposed policy, CMS is now proposing to package the costs from that group of laboratory tests identified in step 4 into the OPSS system rather than paying separately under the Clinical Laboratory Fee Schedule (CLFS).

Using this testing methodology, we calculate an estimated total cost of approximately \$39 million, significantly higher than the range we calculated previously based on the CMS published factors. However, since this analysis is being conducted on data that is used for the proposed rule containing only claims processed through December 31, 2015, this estimate may be incomplete due to the timing required for claims processing. Following similar logic that CMS used in previous years when estimating potential overpayment on clinical labs, we can inflate the estimate by 10% to account for the additional data that is expected to be processed by the time of the final rule. Using this methodology, we get an estimate of approximately \$43 million.

Using the range of \$39-43 million for the cost of the lab tests and the range of \$50 billion to \$63 billion for the total OPSS spending, we compute that the impact of now packaging the unrelated lab tests is between 0.06% and 0.09%, double or triple the estimated impact of 0.03% reported by CMS.

## *Conclusion*

The CMS estimated impact of packaging unrelated laboratory costs may be significantly low, and CMS should review to ensure that payment factors are set properly to account for the costs correctly.