September 6, 2016

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

RE: Proposed Rule: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Procurement Organization Reporting and Communication; Transplant Outcome Measures and Documentation Requirements; Electronic Health Record (EHR) Incentive Programs; Payment to Certain Off-Campus Outpatient Departments of a Provider; Hospital Value-Based Purchasing (VBP) Program (CMS-1656-P)

Dear Acting Administrator Slavitt:

On behalf of our more than 400 hospital and health system members, the California Hospital Association (CHA) is pleased to submit comments on the Centers for Medicare & Medicaid Services (CMS) outpatient prospective payment system (OPPS) proposed rule for federal fiscal year (FFY) 2017.

In summary, CHA:

- Urges CMS to delay implementation of Section 603 in its entirety until it can adequately collect hospital data needed to implement this provision; make the necessary and important system and infrastructure changes to ensure seamless implementation of a new applicable payment system while limiting hospital administrative burden; and identify alternative solutions that promote flexibility for provider-based departments (PBDs) so that services can continue to be provided and access to care maintained while maintaining congressional intent. CHA stands ready to work with CMS to find common sense solutions that promote and maintain access to care for Medicare beneficiaries and create sustainability in an already fragile payment system.
- Urges CMS to exempt hospital-based partial hospitalization services (PHPs) from Section 603 implementation.
- Opposes CMS’ proposal to collapse the current Level 1 and Level 2 APCs into one hospital-based APC for payment of PHPs.
- Supports limited packaging proposal changes related to various modifiers.
- Supports CMS’ proposal to remove the “Pain Management” dimension from the fiscal year (FY) 2018 Hospital VBP program.
- Asks CMS to reconsider the currently proposed measures for the Hospital Outpatient Quality Reporting program.
- Supports CMS’ proposed changes for the Medicare EHR incentive program and recommends additional changes to increase flexibility, reduce burden, and better align hospital and physician requirements.

Our detailed comments are noted below.
IMPLEMENTATION OF SECTION 603 OF THE BIPARTISAN BUDGET ACT OF 2015 RELATING TO PAYMENT FOR CERTAIN ITEMS AND SERVICES FURNISHED BY CERTAIN OFF-CAMPUS PROVIDER-BASED DEPARTMENTS

Section 603 of the Bipartisan Budget Act of 2015 requires that, with the exception of dedicated emergency departments, services furnished or billed for in off-campus PBDs under the OPPS on or after November 2, 2015, would no longer be paid under the OPPS; instead, these services would be paid under other applicable Part B payment systems beginning January 1, 2017.

CMS proposes to implement Section 603 as follows:

1. To create and define the term “excepted items and services” to determine whether items and services are excepted from the Section 603 applicable payment system policy and paid under the OPPS.
2. To define off-campus PBDs and establish requirements for those off-campus PBDs to maintain excepted status, both for the facility and for the items and services it furnishes.
3. To establish payment policies for nonexcepted items and services.

CHA urges CMS to delay implementation of Section 603 proposed policies in their entirety until it can adequately collect data from hospitals needed to implement this provision; make the necessary and important system and infrastructure changes to ensure seamless implementation of a new applicable payment system while limiting hospital administrative burden; and identify alternative solutions that promote flexibility for PBDs so that services can continue to be provided and access maintained while maintaining congressional intent. CHA stands ready to work with CMS to find common sense solutions that promote access and create sustainability in an already fragile payment system.

Excepted Items and Services

As prescribed by statute, CMS proposes that certain off-campus PBDs would be permitted to continue billing for excepted items and services under the OPPS.

Dedicated Emergency Room

CMS proposes that all items and services furnished in a dedicated emergency department, as defined in 42 C.F.R. 489.24 (b), be excepted. CHA supports CMS’ proposal to exempt dedicated emergency departments as defined in 42 C.F.R. 489.24 (b).

On Campus and Remote Location

CMS proposes that on-campus PBDs and the items and services they furnish would continue to be paid under the OPPS. CMS notes that the definition of the term “department of a provider” (as in effect on November 2, 2015) includes both the specific physical facility that is the site of service and the personnel and equipment required to furnish services at the facility. CMS does not propose to change the definition of “campus” under§413.65(a)(2) and believes hospitals may adequately determine whether departments are on campus, including through the provider-based attestation process.

As noted above, Section 603 also provides for an exception for off-campus PBDs that are within the distance described in the definition of campus under §413.65(a)(2). Thus, CMS proposes to exempt those off-campus PBDs located at or within 250 yards from a remote location of a hospital facility from site neutral payments. CHA appreciates that CMS has not
proposed any significant changes to the provider-based regulations and supports CMS’ proposal to continue to allow such determinations to be made at the discretion of the CMS regional office. In addition, CHA applauds CMS for recognizing the remote location and those items and services within 250 yards of a remote location as on campus, therefore meeting the criteria for “excepted” status.

Excepted Status: Services Billed By November 2, 2016

CHA is deeply disappointed in CMS’ narrow read of the statue that has limited the definition of an excepted off-campus PBD to those that submitted a bill for outpatient services under the OPPS on or before November 2, 2015, the date of the law’s enactment. This is particularly troubling because many hospitals in California and around the country find themselves in an untenable situation that we first began addressing with CMS leadership and staff months prior to rulemaking.

For example, Sierra View Medical Center in Portersville, California, opened its doors on October 16, 2015, following a successful survey. However, its license was not issued by the California Department of Public Health until November 1, 2015. Though the hospital saw Medicare beneficiaries beginning October 16, it could not have appropriately billed Medicare for services until November 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. Unfortunately, there are several such instances in California due to the California Department of Public Health’s limited resources and antiquated survey process. In this instance and many others, Sierra View Medical did everything required, but due to delays in a required state process outside the control of the hospital, under the proposed rule they would not meet the criteria for excepted status.

For purposes of payment under the OPPS, section 1833(t)(1)(B)(v) of the Social Security Act excludes certain items and services furnished on or after January 1, 2017, by a provider’s off-campus outpatient department (OPD) (as defined in section 1833(t)(21)(B)) from the definition of covered OPD services. Thus, whether an applicable item or service (as defined in section 1833(t)(21)(A)) is payable under the OPPS or not is determined, in part, on the definition of the term “off-campus department of a provider” under section 1833(t)(21)(B). While clause (i) of section 1833(t)(21)(B) defines the whether a facility is an off-campus PBD based on location (i.e., its location is not on the hospital campus or is within 250 yards of a remote location of a hospital facility), clause (ii) of section 1833(t)(21)(B) excludes from that definition an off-campus PBD based on a timing test, namely whether the facility was furnishing covered OPD services before a certain date. This was intended to permit existing off-campus PBDs to continue to be paid under the OPPS for the items and services they furnish to Medicare beneficiaries.

Specifically, the language of the clause (ii) exception that excludes existing off-campus PBDs from the definition of the term off-campus outpatient department of a provider provides in relevant part the following: “department of a provider (as so defined) that was billing under this subsection with respect to covered OPD services furnished prior to the date of the enactment of this paragraph.”

CMS proposes to interpret this language as meaning that to qualify for the exception, an off-campus PBD must have submitted a bill before the November 2, 2015, enactment date of the Bipartisan Budget Act of 2015 for covered OPD services.

CHA asserts that a broader read of the legislation would allow the agency to appropriately account for examples such as Sierra View Medical Center. More specifically, CHA believes that the agency

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1 As added by section 603(1)(C) of the Bipartisan Budget Act of 2015 (BBA15).
2 As added by section 603(2) of the BBA15.
3 Section 1833(t)(21)(B)(ii) of the Social Security Act, as added by section 603(2) of the BBA15.
has misinterpreted the language of the statute and congressional intent in its proposed implementation of the clause (ii) exception. The exception requires an analysis of several factors, including:

1. Whether the facility is an off-campus PBD under the definition of section 1833(t)(21)(B)
2. If the facility is an off-campus PBD, whether the facility furnished covered OPD services for which payment is allowable under section 1833(t)
3. If the covered OPD service was payable under the OPPS, whether the covered OPD service was furnished before November 2, 2015; and
4. If the covered OPD service was furnished before November 2, 2015, by the off-campus PBD, whether (not when) the off-campus PBD submitted a bill for the service to its Medicare administrative contractor (MAC)

The timing element of the exception (i.e., “prior to the date of the enactment of this paragraph”) modifies the phrase “with respect to covered OPD services furnished.” This is the only logical reading of the sentence. The order of the requirements of the exception makes it clear that the “deadline,” for purposes of qualifying for the clause (ii) exception, applies to the date on which the covered OPD services are furnished. While the clerical billing function of the facility is, of course, an important factor in the analysis of qualification for the exception, it is irrelevant to the analysis of whether the facility was providing covered OPD services before the statutory deadline. Billing may occur some days after a procedure is performed; had Congress intended the billing factor to be the controlling criterion in determining whether a facility met the exception’s timing requirement, it would have worded the provision accordingly. For example, to clearly indicate that the billing was the determinative factor, the exception could have been drafted as follows: “a department of a provider (as so defined) that furnished covered OPD services for which a claim was submitted prior to the date of the enactment of this paragraph.” In both current law and in this example, the timing element immediately follows the operative requirement of the exception which speak to the furnishing of the services — not when the claim for the service was submitted to the appropriate MAC.

The focus on billing as evidence of an off-campus PBD’s eligibility for the clause (ii) exception is misplaced. A hospital’s claim for a covered OPD service furnished to a Medicare beneficiary will include the date(s) on which the service was furnished to the beneficiary. This information provides clear and sufficient evidence that the facility was operational before the November 2, 2015, enactment date. Relying on a facility’s billing operations to satisfy the timing element unfairly penalizes facilities that opened immediately before the enactment of the Bipartisan Budget Act of 2015.

The example of Sierra View Medical Center noted above illustrates this misplaced emphasis. The question is whether the Medicare beneficiary received the covered OPD services from the off-campus PBD before the enactment date not whether the facility’s billing department was fully functional or whether its own processes for billing claims included a standard review period before the claims were submitted to the MAC. The timing element is intended to distinguish between newly acquired or established off-campus PBDs and those that actually furnished covered OPD services on or before November 2, 2015. That test is best met by considering the date of service — not the date a bill for the service was submitted to the MAC.

While we understand CMS has to establish criteria to carry out the clause (ii) exception, we believe it has misread the plain meaning of the language of the clause (ii) exception. The timing element directly follows the phrase that requires furnishing of covered OPD services; it does not directly follow the billing requirement. The plain reading of the legislative language, as well as congressional intent to address
newly created or acquired off-campus PBDs, both support the interpretation that focuses on when a covered OPD service was furnished to a Medicare beneficiary by an off-campus PBD that meets the other criteria of the clause (ii) exception.

Relocation of PBDs
CMS proposes that items and services must continue to be furnished and billed at the same physical address of the off-campus PBD, including the suite number, as of November 2, 2015, in order for the off-campus PBD to keep its excepted status and continue to be paid at the OPPS rates. An excepted off-campus PBD that changes its location will lose its excepted status and be subject to the site-neutral payment policy. CMS requests comment on whether there should be exceptions to this proposal for extraordinary circumstances that are outside the hospital’s control.

Relocation of existing PBDs — moving from on-campus to off-campus and existing off-campus to a new off-campus location — must continue to be paid hospital OPPS rates going forward. This is particularly important to California hospitals due state law requirements on seismic compliance. Further, we believe that an exceptions process requiring CMS’ review and approval is not necessary; we urge CMS to remove barriers for providers that must relocate due to any number of reasons.

California’s hospitals are in the midst of significant campus changes and are rethinking how to provide services in their communities. Until 1973, California hospitals — like most U.S. hospitals — were built to the national Uniform Building Code. A huge building boom from 1968-1972 helped to meet the demands of services that would be provided to Medicare and Medicaid beneficiaries, but the San Fernando Valley’s 1971 Sylmar Earthquake resulted in 50 hospital-related deaths. As a result, the state enacted the Hospital Facilities Seismic Safety Act (HFSSA) in 1973, which required that all new and structurally retrofitted hospital buildings in California be able to remain standing after a major earthquake. However, since the building boom preceded the enactment of state legislation, many hospitals did not have the resources to make necessary changes.

Subsequent earthquakes in 1989, and the famous 1994 Northridge Earthquake — which resulted in over $3 billion in structural and non-structural damages to hospitals — raised significant concerns with the Federal Emergency Management Agency. In response to those concerns, California amended the HFSSA in 1994 to require all hospitals, by 2030, to remain both standing and operational following major seismic activity. The RAND Corporation estimates this mandate to cost California hospitals $110 billion, excluding financing costs.

This standard’s requirements are complex. As hospitals consider how to meet them and engage in the extensive approval process, while still meeting their communities’ needs during the transition, construction experts have recommended less costly options for California hospitals to move on-campus outpatient services to off-campus buildings. In addition to construction costs, land in California is quite expensive, and many of our inner-city hospitals do not have the ability to augment their campus. Compared to the inpatient setting, which is required to withstand a significant seismic event, less stringent building code requirements apply to off-campus buildings. Outpatient building standards are still significantly higher than those for the typical physician office setting; the attached flow chart, developed by the California Office of Statewide Health Planning and Development, details the process for a licensed hospital outpatient department as compared to a physician office building. When outpatient services are provided adjacent to or within the same building as inpatient services, those facilities must comply with the highest and most costly state inpatient standards for seismic building codes. Therefore, hospitals can
utilize their resources more efficiently by providing outpatient services more than 250 yards from an inpatient facility — often adjacent to but technically off-campus — as they plan for the future.

Meeting the 2030 seismic deadlines takes years of planning and multiple state agency approvals that cannot be undone. Hospitals across California are in every stage of development — from drawings, to securing financing, to breaking ground, to moving services to make way for planned construction. For hospitals, the process is similar to homeowners who have renovated their homes while still living in them.

Hospitals are held accountable by the regulatory agencies that oversee these massive projects as well as the creditors and the communities that support the financing of these construction costs. Allowing relocation of existing on-campus services to off-campus locations, and existing off-campus locations to move to new off-campus locations, is critical if California’s hospitals are to continue providing essential services in their communities and keep on track with their planned seismic compliance without unraveling years of planning and agreed-upon financing.

As detailed in our March meetings with staff and subsequent June correspondence to CMS, the University of California (UC) Davis Medical Center is in the process of relocating a number of services that are currently provided in the North South Wing of the Medical Center, which is being phased out because it will not meet the 2030 seismic requirements. These existing PBDs, including hospital-based pulmonary rehabilitation and pulmonary function testing labs, as well as gastroenterology and neurology, need to be relocated to new locations or existing off-campus locations. The services’ transition has been planned for more than three years, and they are scheduled to be moved to existing hospital-based off-campus space as well as a new off-campus location — both more than 250 yards from the main campus — later this summer. Without regulatory flexibility afforded by CMS under this proposed rule, UC Davis will be in the untenable position of having to comply with state mandates that required a huge investment of resources, yet subject to loss of its OPPS reimbursement rate because it had no choice but to move. Unfortunately, they are not alone.

To adjust to the changing health care environment, Palomar Health located in San Diego, California, is consolidating services and closing the Palomar Health Downtown Campus (PHDC), which became home to many outpatient services after the new Palomar Medical Center opened in 2012. Due to increased costs to maintain this facility under the new seismic requirements, among other factors, the Palomar Health Board of Directors voted in June 2015 to close PHDC, which shares a license with Palomar Medical Center, and relocate the services to other facilities within the system but off the hospital campus. These services include radiation therapy, cardiac rehabilitation and its sleep lab. Similar to UC Davis, Palomar Health has been working with the California Office of Statewide Health Planning & Development and the California Department of Public Health since July 2015 to secure the necessary approvals to move and license these services as required by state and federal regulations. The regulatory process in California is quite lengthy, making the enactment date for Section 603 particularly problematic for Palomar Health. Palomar Health’s relocated sleep lab was ready to open, awaiting the state’s final inspection when the BBA was enacted on November 2, 2015. If finalized, these existing PBDs will be classified as new off-campus outpatient departments, despite the fact that these are simply being relocated off the hospital campus. We believe this is counter to the legislation’s intent, as these were existing services paid under OPPS but that must relocate in order to preserve access to these services in the community.

These are just a few of the examples of existing PBDs that cannot and should not be frozen in time. These are not examples of acquisition of services, nor are they expansions of services. These hospitals and health systems have legitimate reasons for moving, and as such we urge CMS to allow for maximum flexibility for relocation of existing PBDs — both those that exist on- and off-campus.
In the proposed rule, CMS acknowledges that some circumstances may require a facility move, such as natural disasters or federal or state requirements. CMS seeks comment on whether it should develop a “clearly defined, limited relocation exception process, similar to the disaster/extraordinary circumstance exception process under the Hospital VBP program.” CMS also seeks comment on other circumstances beyond the hospital’s control that should be considered for additional exceptions.

As detailed above, relocation is critical in preserving access to needed services for Medicare beneficiaries. CHA believes strongly that Congress intended this legislation to curb what it believes to be the inappropriate acquisition of physician practices for the purposes of enhanced payment, not to freeze health care services in their current place for all eternity. Not only does this proposed rule freeze those services currently provided in off-campus PBDs, it also essentially freezes all PBDs — even those currently on-campus. CHA urges CMS to reconsider its approach and take additional time to identify common sense solutions that will allow appropriate tracking of PBDs, remaining consistent with the legislation’s intent.

Creating a list of reasonable circumstances in which it would be common for a provider to have to relocate a PBD and establishing an attestation process would be sufficient. We ask that CMS not create processes burdensome to both CMS and to providers, but rather assume that relocation is necessary and that providers would alert CMS to such changes, similar to the current process already in place. Notably, CMS may consider additional periodic oversight to ensure the attestation process is operating as expected without subjecting providers to a specific approval process, especially when relocation can be a time sensitive issue for a provider.

Finally, in our experience in California, we believe it would be incorrect to assume that physicians and other clinicians will step in and fill the gap left by hospitals and health systems in providing access to services for Medicare and Medicaid beneficiaries, the uninsured and under insured. California is experiencing tremendous growth in our insured population, while one in three Californians is enrolled in Medicaid. This presents significant challenges for our health care system. Health insurance coverage does not equal access to care; California’s emergency departments are overflowing with patients due to the lack of access to services in the community. Hospitals and health systems across California have identified areas of greatest need and are working to address those needs — relocation of services is a critical component in ensuring that services are brought to those in the community who need it most.

Expansion of Clinical Family of Services
CHA, along with other stakeholders, expressed a desire to expand the number or type of services that an excepted off-campus PBD could furnish and still maintain excepted status. CMS believes the statute requires a reading that to maintain excepted status, an off-campus PBD is limited to offering services only within the clinical family of services it furnished before November 2, 2015. CMS proposes to clarify that services furnished that are not part of the clinical family of services billed before November 2, 2015, would not be payable under the OPPS. Further, CMS proposes to define service types by 19 clinical families of hospital outpatient service types described in Table 21 of the proposed rule. CHA is deeply disappointed in this approach, as it makes an implementation of an already complicated policy even more problematic.

First, we do not believe the legislation nor Congress intended for specific services as defined at the APC level within the PBD to be treated differently. Notably, in the proposed rule, CMS inconsistently applies the current provider-based regulations creating unnecessary and administratively burdensome complexities. As noted in Transmittal A03030 released in 2003
CMS clearly states that the definition of a PBD is site-specific, not service-specific.

1. Does a main provider have to submit a separate attestation for each of its facilities and services, on campus and off campus?

*The provider-based rules do not apply to specific services; rather, these rules are site-specific. That is, each individual department or entity in its entirety must be a subordinate and integrated part of the main provider...*For purposes of provider-based determinations, a facility may be an entire building, two or more buildings, or defined areas within a building. For example, a hospital may lease space in a building that includes numerous physicians’ offices, a DME supplier, and some other non-medical offices, in addition to housing the hospital’s radiology department and an outpatient clinic. Provider-based status would only apply, however, to the radiology department and the outpatient clinic. Because the provider-based rules are site-specific, the provider would attest to the provider-based status of the radiology department and the outpatient clinic. *That is, the provider would attest that each department or entity within that multi-suite building to which the provider-based rules apply, meets the provider-based rules.* The provider would not attest that the entire building is provider-based, but only that those specific offices or suites where hospital services are provided are provider-based. A provider may need to submit floor plans of such a building in order to document that a department or entity is provider-based.

CHA opposes CMS’ proposal to further define PBDs at the APC level as proposed in Table 21 of the proposed rule. We believe that this is an ill-conceived application of the law and the current provider-based regulations as specified in 42 CFR 413.65 (a)(2). Further, Table 21 as outlined in the proposed rule is distressingly inaccurate. For example, CMS has failed to list a number of services including partial hospitalization, drugs and other services. We respectfully ask that CMS withdraw this policy, as we are very concerned about the added complexity and inconsistent application of the regulations across PBDs.

In addition, CMS considered — but did not propose — requiring a specific time frame during which service lines had to be billed under the OPPS (e.g., 2013 through November 1, 2015). We agree with CMS that there should be no limit on volume of services; however, CHA opposes any proposed look-back period for which service lines had to be billed under OPPS. We remain very concerned that this particular proposal is significantly shortsighted, and that this proposed rule sets forth unsustainable policies. Moreover, this particular proposal is inherently complex for the agency to administer and to maintain and will, in addition to the expansion of services policy noted above, introduce extraordinary complexity to the billing of services provided in nonexcepted PBDs (discussed in more detail below).

*Change in Ownership*

CMS notes that current policy provides that if a participating hospital, in its entirety, is sold or merged with another hospital, a PBD’s provider-based status generally transfers to the new ownership if the transfer does not result in material change of the provider-based status. Consistent with that policy, CMS proposes that the excepted status of an off-campus PBD would transfer to new ownership only if (1) the main provider is also transferred, and (2) the Medicare provider agreement is accepted by the new owner. CHA supports this proposal.

**CMS also proposes that an individual excepted off-campus PBD that is transferred from one hospital to another would lose its excepted status. CHA does not support this proposal. Similar to**
its approach of freezing in place all PBDs, this policy stands to have the unintended consequence of limiting access for beneficiaries. For example, in California, a number of our small and rural hospitals operate off-campus PBDs, which are essential in maintaining access to care for beneficiaries across minimally populated areas. These clinics often operate at a loss to the organization but, despite being a loss leader, are essential in maintaining physician presence in rural communities that do not attract as many physicians as more profitable urban areas. Many rural hospitals are under significant financial stress will be faced with tough choices in the future, which may include selling one of their off-campus PBDs in order to remain financially viable. CHA believes strongly that allowing a PBD to maintain its excepted status is appropriate and, in many instance, necessary to ensure access to services in communities across California. Loss of excepted status will likely result in the closure of many PBDs; those in rural communities will disproportionately be impacted.

Data Collection

CMS notes that, due to limited ability to link enrollment and claims files, it is currently unable identify (1) all individual excepted off-campus PBD locations, (2) the date each such PBD began billing and (3) the clinical families of services provided by each such PBD before November 2, 2015. These are essential data elements needed for seamless implementation. Notably, CHA does not believe that, even if this information was known today, CMS would be ready to implement this provision by January 1, 2017. As previously stated and detailed below, we strongly urge CMS to delay this provision’s implementation in its entirety until no earlier than January 1, 2018.

PAYMENT FOR NONEXCEPTED OFF-CAMPUS PBDS

While CMS notes in the proposed rule that it intends to develop a mechanism for an off-campus PBD to bill and be paid for furnishing nonexcepted items and services under the “applicable payment system,” it states that there is no straightforward way to do that before January 1, 2017. Therefore, CMS proposes to make no payment to “nonexcepted” off-campus PBDs for services furnished to Medicare beneficiaries beginning January 1, 2017. Such a policy is ill-advised and shortsighted. We urge CMS to delay implementation until a more reasonable and considered approach can be fully considered and vetted with all stakeholders.

We agree that CMS needs additional time to make changes to complex systems that are inherent in the course of accurate and timely claims processing. However, time taken to address these fundamental payment policy and infrastructure problems should not be borne by the hospital off-campus PBD that just happened to have opened its doors and billed for services after November 2. Ensuring that communities have access to all necessary health care services takes collaboration with community partners and a strategic vision. Plans were made long before the legislation passed, and the additional uncertainty of rulemaking should not be compounded by an entire year of non-payment. Access to services will be compromised and many hospitals across California will have to discontinue providing services if faced with non-payment.

CMS has a long history of delaying implementation of federal law when additional time is needed to collect data, update the complex billing systems and think through a number of policy questions that, if unaddressed, will lead to an administratively burdensome and costly implementation. Most recently, CMS delayed implementation of congressionally mandated revisions to the Clinical Lab Fee Schedule for a period of one year.

Additional time allows the agency to collect needed data, engage with stakeholders and set forth a plan for seamless implementation. CHA stands ready to work with CMS and other stakeholders in
clearly enumerating these challenges and working to resolve them in the most efficient and administratively feasible way possible.

Calendar Year 2017 Applicable Payment System

CHA does not support CMS’ interim proposal to use the Medicare Physician Fee Schedule (MPFS) as the applicable payment system for the majority of nonexcepted services furnished during 2017 or in the future. CHA believes strongly that such an approach is unworkable for many reasons, discussed in further detail below. Notably, CMS should consider alternatives to the MPFS for purposes of implementing this legislation beginning no earlier than calendar year (CY) 2018.

More specifically, beginning January 1, 2017, CMS proposes that physicians furnishing services in off-campus PBDs would be paid based on the professional claim and at the non-facility rate for services for which they are permitted to bill. CMS proposes that there would not be a separate facility payment to the hospital for nonexcepted services furnished during 2017. CMS does not believe there is a way for off-campus PBDs to bill for those nonexcepted services furnished during 2017, and notes it is exploring options to permit billing for these services beginning in 2018.

Paying physicians at the non-facility rate in the absence of a facility payment to the PBD is untenable and jeopardizes access to care for Medicare beneficiaries. Further, such a proposal is particularly problematic in a state like California, which prohibits the corporate practice of Medicine, and, as such, has inherently complex contracts with physicians that cannot be reconciled with this proposed payment policy by January 1, 2017. CMS seeks comments on the impact of the reassignment rules (§424.73), the anti-markup prohibition (§414.50) and the physician self-referral prohibition (§§414.350 - 389) to compensation arrangements, as well as the anti-kickback statute (§1128B(b) of the Act) on arrangements, between hospitals and physicians and non-physician practitioners.

California’s hospitals must be particularly mindful of both federal and state laws that govern these relationships as the traditional employment model is not available to them; as such, the burden of collaboration is significantly higher in California. As it stands currently, there is absolutely not enough time to even begin to think through — let alone finalize — a new set of contract provisions that would ensure compliance and appropriate payment under state and federal laws and ensure continued operation of these services. CHA fully supports the comments submitted by the American Hospital Association in its analysis of this payment policy’s impact on federal law, and believes that this complicating factor is just one of many that supports a logical conclusion to delay implementation until no earlier than CY 2018.

In addition, CHA is very concerned that CMS has proposed the MPFS as the applicable payment system without fully contemplating the operational challenges for hospitals and a complete and robust analysis of existing payment policies that will overlay both existing excepted and nonexcepted PBDs. The impact is significant for beneficiaries who may receive two separate bills with separate co-payments, further adding confusion to an already complex issue.

For example, California hospitals have expressed concern over how claims will need to be submitted and processed when services are provided on the same day in both excepted and nonexcepted PBDs. The complexities of the OPPS packaging policies, the three-day payment window and claims processing and transaction standards must all be addressed prior to implementation. Further, there are downstream impacts with secondary and commercial payers and implications
for Hospital Outpatient Quality Reporting (OQR) program measures. Current OQR measures are derived from the hospital claims, not the physician claims. The list of issues goes on and on.

CHA stands ready to engage with CMS and the broader hospital community to develop a comprehensive list of challenges and then begin the hard work of problem solving. Such a process will greatly inform CMS’ next steps and, we believe, likely lead to the development of a new applicable payment system for nonexcepted PBDs that is a hybrid of the existing payment systems, minus some of the arcane billing rules that may no longer be necessary. At this time, we do not agree that moving hospitals from the institutional claim (UB04) to a CMS 1500 is appropriate or feasible. Updating systems and training staff will cost the health care system far more than it would Medicare to update its current claims processing infrastructure. CHA urges CMS to think beyond the short term and consider the long term sustainability of such a system going forward.

Partial Hospitalization Services and Applicable Payment System
While limited in number, outpatient PHPs furnished under OPPS are critically important and reduce the burden on inpatient psychiatric and acute care providers, many of which are at capacity in California. CHA urges CMS adopt a clear policy that the provisions of Section 603 and its implementing regulations do not apply to PHPs, including those that may open after November 2, 2015 (nonexcepted PHPs). Absent such an exemption, CMS risks placing a moratorium on new PHP programs, which have no comparable “physician office” service. PHPs are essential to providing stable and reliable behavioral health programs in across California where access to behavioral health services is at capacity or significantly limited. PHPs help to keep beneficiaries out of the inpatient setting, at far less cost to the Medicare program; steps must be taken to maintain these programs.

The partial hospitalization benefit was created for a very vulnerable population and serves as an important intermediate service between outpatient, office-based visits and inpatient psychiatric care. Patients who meet the admission criteria for partial hospitalization services are in need of an intensive, highly structured day of therapeutic services. They receive at least three and usually four or more interdisciplinary professional services (either individual or group sessions) individualized to meet the goals of their specific treatment plan. The therapies are designed to provide a highly integrated approach to treatment, with each intervention supporting the overall needs of the individual patient. Patients typically attend the program four to five days a week for an episode of care that averages about 12 treatment days.

CHA is deeply concerned that CMS’ approach to implementing Section 603 will completely erode an already fragile safety net for Medicare beneficiaries who rely on these programs in order to remain in the community and out of the inpatient setting. As previously stated, Congress made it very clear that Section 603 was intended to curb acquisition of physician practices and that any site-neutral policy is to not pay more for the same service, regardless of the setting. No service provided in the physician office setting or in any other setting is comparable to those provided by PHPs.

PHPs have their own set of unique coverage guidelines, many prescribed in statute. Absent OPPS rates, these programs stand to become a significant financial burden and could threaten the viability of the larger organization. We disagree with CMS that having providers reenroll as community mental health centers (CMHCs) is an appropriate option.

As CMS is aware, CMHCs require separate certification, operate under separate conditions of participation, and operate in a way that is distinctly different from an off-campus PBD. Hospital-based
PHPs offer significant advantages over CMHC PHPs, which CMS itself has identified. According to a report commissioned by CMS, 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) typically have easier access to more support staff, nutritionists, nurses and psychiatrists; and (4) have the “obvious” advantage in timely and safe re-admission to an inpatient unit.4 In other words, the proposed solution — that these entities transition to a different provider type — ignores both the inherent structure of hospital-based PHPs, as well as their inherent benefits.

Rather than crafting a new payment system for hospital-based PHPs, or forcing hospital-based PHPs into a payment system that was not designed for that purpose, we strongly believe that public policy necessitates excluding hospital-based PHPs from Section 603 and any final regulations, so as to permit new, nonexcepted PHPs to bill under OPPS.

Adding insult to injury, College Hospital Cosa Mesa learned that its off-campus provider-based hospital outpatient department, which serves as the area’s only PHP for patients with significant behavioral health conditions, is up for a lease renewal. The owner of the building is currently proposing to move the PHP clinic into another suite in the same building so the landlord can more efficiently utilize the space. This is change is not at the request of the hospital. The landlord has requested a long-term lease renewal to secure the PHP clinic spot in the building. However, under CMS’ relocation proposal, College Hospital would lose its ability to be paid hospital-specific APC rates for an existing PHP because it currently anticipates a suite number change.

Should CMS chose to finalize its relocation policy, College Hospital would no longer be able to receive OPPS payments and may have no choice but to close this PHP clinic, thereby exacerbating an already existing shortage of services for our patients with behavioral and mental health needs. CHA urges CMS to reconsider and continue to pay PHP providers at OPPS rates for CY 2017 and beyond.

**PROPOSED CHANGES TO PHP RATE SETTING**

As noted above, PHPs are intensive outpatient psychiatric programs providing outpatient services in place of inpatient psychiatric care. PHP services may be provided in either a hospital outpatient setting or a freestanding CMHC. PHP providers are paid on a per diem basis with payment rates calculated using CMHC- or hospital-specific data.

Beginning with CY 2017, CMS proposes to combine the existing two-tiered PHP APCs into a single APC for each setting. Payments for the new APCs would be calculated by combining the geometric mean per diem costs for existing Level 1 and Level 2 PHP APCs into a single value for the new, aggregated APCs. CMS states that these newly combined APCs would avoid further cost inversion issues (Level 1 geometric mean per diem cost greater than that of Level 2), and would thus generate more appropriate payment for the services provided. Another reason behind the aggregation is the decrease in the number of PHPs, particularly CMHCs. In a smaller pool of providers, data from the large providers would have a more pronounced effect on the calculated payment rates and is magnified further by splitting services into separate levels of APCs.

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The table below compares the final CY 2016 and proposed CY 2017 PHP payment rates:

<table>
<thead>
<tr>
<th>Proposed CY 2017</th>
<th>Final CY 2016</th>
</tr>
</thead>
</table>
| APC 5853: Partial Hospitalization (3+ services) for CMHCs | APC 5851: Level 1 Partial Hospitalization (3 services) for CMHCs  
APC 5852: Level 2 Partial Hospitalization (4+ services) for CMHCs |
| $135.30  
$94.49  
$143.00 | $129.45  
$94.49  
$143.00 |
| Geometric Mean Per Diem Cost | Payment Rate | % Change (2017) |
| $192.57  
$183.41  
$212.67 | $184.25  
$183.41  
$212.67 | -  
+0.5%  
-13.4% |

CHA strongly opposes any changes to the Level 1 and Level 2 APCs for hospital-based PHP programs. As evidenced by CMS’ own analysis, these programs are decreasing in number, illustrating the challenge in maintaining these essential programs when costs continue to increase but payments continue to decrease.

A number of our inpatient psychiatric facilities (IPFs) that operate hospital-based PHPs, have noted the critical role these programs play in keeping patients out of the inpatient setting, and therefore keeping those beds available for our most critically ill patients in need of inpatient care. These programs are far more cost effective than emergency room or inpatient treatment; any reduction in payment jeopardizes an already less than profitable service.

In addition, in California, many of our PHPs do operate and bill for Level 2 services, which — if this policy moves forward — will result in a 13.4 percent decrease in payments for these services. These programs will be disproportionately impacted, as opposed to those programs that operate and bill for Level 1 services. If PHPs cannot continue to provide services, this will create a downstream impact on other providers. Further, closure of one PHP will increase the cost to another PHP, as patients will need to be transported — perhaps spending 45 to 90 minutes in a transport van each way to get the services they so desperately need.

Medicare beneficiaries who participate in these programs are our most vulnerable. Despite CMS’ analysis of the claims data, we believe this program is currently cost effective and must be preserved. Should CMS choose to proceed despite our strong objections, we ask that a transition be considered to mitigate the impact to those providers that are currently serving our most acutely ill patients.

**PROPOSED CHANGES TO PACKAGING POLICIES**

Under current policy, certain clinical diagnostic laboratory tests that are listed on the Clinical Laboratory Fee Schedule (CLFS) are packaged in the OPPS as integral, ancillary, supportive, dependent or adjunctive to the primary service or services provided in the OPD. For 2017, CMS proposes two changes to the laboratory test packaging policy.

CHA supports CMS’ proposal to discontinue the unrelated laboratory test exception and the associated “L1” modifier that designates separate payment. This modifier has long been a subject of numerous hospital open door forums and has led to tremendous confusion in the field. With this change, CMS proposes to package any and all laboratory tests that appear on a claim with other OPD services. We agree with CMS that in most cases, “unrelated” laboratory tests are not significantly
different than most other packaged laboratory tests provided in the hospital OPD. However, with that said, we urge CMS to be as transparent as possible in its empirical analysis of this policy to ensure that payments are not decreased inappropriately. We are concerned that CMS may have underestimated the payment impact of this proposal on providers. CHA has long been concerned about the growing complexity of CMS packaging policies and the agency’s ability to accurately capture them in the payment system. Transparency is essential as CMS endeavors to pay accurately for services provided.

CHA does not oppose CMS’ proposal to expand the molecular pathology test exception to include all advanced diagnostic laboratory tests (ADLTs) that meet the criteria of section 1834A(d)(5)(A) of the Affordable Care Act. Under the proposal CMS would assign status indicator “A” (separate payment under the CLFS) to laboratory tests designated as ADLTs under the CLFS. Because these tests are so limited, we urge CMS to carefully monitor this transition.

UPDATES TO THE INPATIENT-ONLY LIST
The inpatient list specifies services/procedures that Medicare will only pay for when provided in an inpatient setting. CMS seeks public comment on the possible future removal of CPT code 27447 — total knee arthroplasty (TKA) — from the inpatient-only list. Specifically, CMS seeks comment on how to reflect the shift of some Medicare beneficiaries from inpatient TKA to outpatient TKA due to the Bundled Payments for Care Improvement Initiative (BPCI) and Comprehensive Care for Joint Replacement (CJR) methodologies.

CHA believes it would be premature for CMS to consider removal of CPT code 27447 from the inpatient-only list at this time; therefore, we urge CMS not to propose such a policy in the near term. While we see advances in treatment in the traditionally insured commercial population, we are concerned that TKA remains a complex procedure, in particular for the Medicare population. We urge CMS to proceed cautiously in making the clinical decision to move this procedure to the outpatient setting.

Further, California currently has 135 hospitals in three metropolitan statistical areas that are subject to the mandatory CJR episode payment model, along with numerous providers voluntarily participating in BPCI. Hospitals are currently planning — and many have spent months laying the ground work for — successful partnerships with physicians and other post-acute care providers. These agreements are largely based on current CJR program rules, anticipated volume of the inpatient procedures and CMS’ proposed spending targets. Removing TKA from the inpatient-only list will undermine that planning and require significant changes in assumptions. CHA urges CMS to consider additional stakeholder input and alternative program changes to CJR and BPCI before proposing this change. Alternatives may include changes in the CJR and BPCI episode risk-adjustment methodology or the target price and reconciliation process. Additional time is needed to fully understand all the complicating issues that may arise.

APPROPRIATE USE CRITERIA FOR IMAGING
The Protecting Access to Medicare Act required that, by January 1, 2017, payment be made only to the furnishing professional for an applicable advanced diagnostic imaging service if the claim indicates that the ordering professional consulted with a qualified clinical decision support mechanism (CDSM) as to whether the ordered service adheres to applicable appropriate use criteria (AUC). As finalized in the CY 2016 MPFS final rule, CMS is implementing the requirement in incremental stages, and therefore will not require providers to consult AUC by the statutory deadline of January 1, 2017. In the CY 2017 MPFS proposed rule, CMS proposes requirements for qualified CDSMs and states its plans to announce the first
list of qualified CDSMs no later than June 30, 2017. CMS further anticipates that furnishing providers could begin reporting AUC information starting January 1, 2018. In addition, CMS states its intention to propose procedures for capturing consultation of the qualified CDSM on claims forms in the CY 2018 PFS rulemaking cycle.

As detailed in our MPFS comments to CMS, CHA continues to support the AUC program’s described goal of promoting the evidence-based use of advanced diagnostic imaging to improve quality of care and reduce inappropriate imaging. In addition, we appreciate that CMS is taking an incremental approach to implementation of such a significant program. However, we remain concerned that an implementation date of January 1, 2018, will still be too early for hospitals to make the necessary investments in technology, adjustments to workflow and changes within billing departments to be successful. CHA appreciates CMS’ consideration of these comments, as well as others that were submitted under separate cover, which are available on our website at www.calhospital.org/cy2017-pfs-proposed-comments.

HOSPITAL VALUE-BASED PURCHASING (VBP) PROGRAM - HCAHPS CHANGES

In this CY 2017 OPPS/Ambulatory Surgical Center (ASC) proposed rule, CMS proposes to remove the Pain Management dimension of the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey for purposes of the Hospital VBP program, beginning with the FFY 2018 program year. CMS notes that it has received feedback that stakeholders are concerned about the pain management dimension questions being used in HCAHPS survey — particularly their impact on the Hospital VBP program and the unintended consequences of creating an incentive to prescribe more opioids in order to achieve higher scores on this dimension.

CHA strongly supports CMS’ recent actions to recognize stakeholder concerns about these measures and its proposal to remove them from the Hospital VBP program in FFY 2018. CHA has long advocated that only the most reliable and valid measures should be included in performance based improvement programs where Medicare payment is at risk, and appreciates CMS’ steps to address provider concerns. **We agree and continue to support efforts to publicly report these measures. However, CHA does not support CMS’ efforts to translate the reporting into a five-star rating.**

While CHA strongly supports public reporting of measures that are reliable, valid and provide meaningful comparisons among hospitals, we do not believe the current CMS five star methodology accurately depicts the quality of care provided to patients. As such, we urge CMS to further reconsider its approach in displaying measures using the current methodology, and, at a minimum, consider excluding these two specific HCAHPS measures from inclusion in any methodology.

CHA looks forward to the results of CMS’ efforts to develop and test alternative questions related to provider communications and pain, and we stand ready to work with CMS to ensure that the measures are meaningful to both patients and providers.

HOSPITAL OUTPATIENT QUALITY REPORTING PROGRAM

CMS proposes changes to the Hospital Outpatient Quality Reporting (OQR) program including adoption of seven new measures beginning with the 2020 payment determination. In addition, CMS proposes to change the deadline for extraordinary circumstances exemptions.

*Admissions and Emergency Department Visits for Patient Receiving Outpatient Chemotherapy Treatment*

This claims-based measure aims to reduce the number of potentially avoidable inpatient admissions and emergency department visits among cancer patients receiving chemotherapy in the outpatient department, and includes calculation of two mutually exclusive outcomes within 30 days of receiving...
such services:
- One or more inpatient admissions
- One or more emergency department visits for any of ten diagnoses (anemia, dehydration, diarrhea, emesis, fever, nausea, neutropenia, pain, pneumonia or sepsis)

The measure’s two components would each be risk-standardized rates calculated as the ratio of predicted to expected outcomes multiplied by the national observed rate. CMS notes that the Measure Applications Partnership (MAP) conditionally supported the measure, pending National Quality Forum (NQF) endorsement, with special consideration for sociodemographic status (SDS) adjustments and the selection of exclusions.

CHA is disappointed that CMS continues to present very limited analysis of the appropriateness of SDS adjustments for measures generally. Measure developers currently limit their testing to one or two variables rather than fully exploring the breadth and depth of a hypothesis that SDS impacts the outcomes of care, —particularly on specific outcome measures that we believe are largely impacted by the availability of and access to appropriate and timely follow up care in the community.

**CHA supports efforts by CMS and its measure developers to quantify the number of potentially avoidable admissions and visits among cancer patients. However, we believe this measure falls short in truly representing the quality of care provided to cancer patients. CHA believes this measure should be evaluated by the NQF for endorsement prior to being adopted into a public reporting program, as careful review of the risk adjustment and appropriate exclusions is needed. In addition, CHA asks that CMS proceed cautiously in implementing these measures and consider additional testing and evaluation as it progresses. Lastly, we respectfully request that CMS rethink its approach to the measures’ evaluation for SDS, and consider additional exclusions to this measure going forward.**

Finally, the hospital community, including CHA, has long been skeptical of the ability of claims-based measures to accurately capture the clinical complexities of patients. Due to the inherent nature of cancer care, we believe that measures will be particularly challenging for hospitals to improve upon as it will not be entirely clear whether a negative outcome (i.e. admission or ED visit) is truly a result of a complication of chemotherapy or the disease’s progression. CHA remains deeply concerned about measures such as this, as well as hospitals’ ability to meaningfully improve on such measures.

**Hospital Visits after Hospital Outpatient Surgery (NQF #2687)**

The specific outcomes measured are inpatient admissions directly after the surgery and unplanned hospital visits defined as an emergency department visit, observation stay or unplanned hospital admission within seven days of the surgery. If more than one unplanned hospital visit occurs, only the first visit is counted in the measure. This proposed measure was endorsed by the NQF in September 2015 after significant debate and an appeal by provider groups due to the current measures’ overlap with existing OQR measure Op-32: Facility Seven Day Risk Standardized Hospital Visit Rate After Outpatient Colonoscopy.

The MAP supported its inclusion in the OQR, but noted that NQF endorsement occurred prior to the start of the SDS trial period and should be re-examined during measure maintenance to determine whether SDS adjustments are needed. **CHA supports the MAP’s recommendation and asks that CMS more fully examine this measure for SDS adjustment. Further, as noted above, we believe CMS and its measure developers must more comprehensively evaluate these measures.**
However, as that evaluation may be informed by work undertaken by the Office of the Assistant Secretary for Planning and Evaluation, we believe it would be premature to move forward with implementation at this time. In addition, CHA believes the measure to be particularly challenging for this program due to its current overlap with OP 32, as noted above. While we appreciate that CMS has harmonized the measure methodology, it is still a duplicative measure.

CHA, MedPAC and others have expressed growing concern over the number of measures being adopted in these programs. While we do not believe this to be the most critically important measure for consideration in this program, we would urge CMS to limit the duplication of OP-32 and consider only one of the two measures for inclusion in this program.

**Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems**
The OAS CAHPS survey contains 37 questions covering access to care, communications, experience at the facility and interactions with facility staff. Voluntary implementation of the OAS CAHPS began in January 2016; however, the current number of participants and the outcomes of that reporting are not yet known. Five OAS CAHPS-based measures are proposed for addition to the OQR program for 2020 payment. The proposed measures include three composite measures, each of which consists of at least six OAS CAHPS survey questions, and two global rating measures, based on one survey question each.

- OP-37a: OAS CAHPS – About Facilities and Staff
- OP-37b: OAS CAHPS – Communication About Procedure
- OP-37c: OAS CAHPS – Preparation for Discharge and Recovery
- OP-37d: OAS CAHPS – Overall Rating of Facility
- OP-37e: OAS CAHPS – Recommendation of Facility

CHA appreciates and applauds CMS’ continued focus on measures related to patient experience of care as part of its measure development portfolio. However, we have some significant concerns on the proposed administration methods for the OAS CAHPS survey, as well as the proposed timing of implementation.

Unfortunately, the OAS CAHPS is not currently NQF-endorsed and, to our knowledge, has not yet been submitted for review. CHA agrees with the MAP recommendation that encouraged continued measure development. While CMS reports that stakeholder input on the survey was received through a January 2013 request for information as well as a technical advisory panel, we are not convinced that there has been sufficient testing. In addition, the evaluation of the voluntary reporting effort would further assess the readiness of this measure for implementation.

CMS also proposes that hospitals would be required to contract with a CMS-approved vendor to collect survey data on a monthly basis for quarterly reporting. Data would be collected during CY 2018. Hospitals would be required to survey a random sample of eligible patients each month and, over a 12 month period, collect at least 300 completed surveys — in addition to the 300 surveys that must be collected for the inpatient HCAHPS survey.

While we strongly support efforts to capture patient experience, we are disappointed that CMS has not fully explored and tested alternative data collection methods that would significantly decrease providers’ cost in administering the survey and likely enhance patient participation. More specifically, CMS proposes the same methodology as it has for all its surveys — mail and phone. CMS has intently focused on patient engagement through multiple HITECH efforts, most notably the EHR Incentive program, but
has neither allowed for nor, to our knowledge, tested the OAS in an online format as an appropriate mode of administration of this survey.

CHA believes strongly that, before we create a new cottage industry of CMS vendors wishing to assist hospitals, we should develop and test an open and publicly available online survey tool that can be implemented by providers at a significantly reduced cost. This presents providers with tremendous opportunities, including adding such a survey to communications about follow up tests and appointments and linking results within the EHR.

CHA strongly urges CMS to rethink its approach and consider delaying this survey until an electronic, online approach is an option for hospitals. There is tremendous opportunity to do this now, rather than wait and reconcile the old approach with a new one in the future. CHA stands ready to work with CMS to accomplish these goals.

Extension for Extraordinary Circumstances Exemption Request Deadline

CHA supports CMS’ proposal to extend the extraordinary circumstances exemption request deadline, for both chart-abstracted and web-based measures, from 45 days to 90 days following an event causing hardship.

PROPOSED CHANGES TO THE MEDICARE AND MEDICAID EHR INCENTIVE PROGRAMS

CMS proposes a number of changes to the Medicare EHR Incentive programs for eligible hospitals and critical access hospitals (CAHs) intended to increase flexibility, reduce burden, and better align hospitals with the Merit-Based Incentive Payment System’s (MIPS’) new physician EHR requirements. CHA appreciates that CMS has taken steps toward flexibility in response to concerns from the hospital community. However, we continue to have concerns over a number of the proposed objectives and thresholds, as well as the requirement that hospitals report for a full calendar year by 2017.

CMS notes that it understands more time is needed to accommodate updates in the 2015 EHR Incentive program final rule and, as a result, proposes a continuous 90-day reporting period in 2016 for all returning eligible providers (EPs), eligible hospitals and CAHs that have previously demonstrated meaningful use in the Medicare and Medicaid EHR Incentive programs. In conjunction with this proposal, CMS proposes to establish a 90-day reporting period for electronic clinical quality measures (eCQMs) for all EPs, hospitals and CAHs that choose to report eCQMs by attestation in 2016. CHA appreciates that CMS has responded to hospital comments that a 90-day reporting period is necessary to accommodate and implement changes from the 2015 EHR Incentive program’s final rule. CHA also supports the alignment of a 90-day reporting period for eCQMs. However, CMS continues its policy that hospitals will be required to report on a full calendar year in 2017. CHA urges CMS to also adopt a 90-day reporting period for 2017 and, whenever program requirements are updated or the definition of certified EHR changes, to include a new edition of technology or new functionality. Hospitals need time to adequately transition their technology and ramp up to increasing threshold requirements.

In addition, CMS proposes to apply any proposed changes to EHR Incentive program requirements only to Medicare — not to Medicaid. CHA recommends that CMS also apply the finalized changes to hospitals 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. In the proposed rule, CMS expresses concern about states’ ability to modify their receiving systems on a short time frame. However, we believe that a 90-day reporting period for 2017 and any subsequent years, would address these concerns and ensure 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.

CMS also proposes to eliminate the Clinical Decision Support (CDS) and Computerized Provider Order Entry objectives and measures for eligible hospitals and CAHs attesting under the Medicare EHR Incentive program for Modified Stage 2 and Stage 3 for 2017 and subsequent years, which would align hospitals with physician objectives in the Advancing Care Information category of MIPS. **CHA appreciates that CMS is taking steps to align objectives and measures for hospitals and MIPS-eligible clinicians. In addition, CMS notes that both objectives currently attain high levels of achievement so they are no longer useful in comparing performance. CHA has long supported the removal of topped out measures and has opposed the link between CDS and eCQMs. CHA appreciates CMS’ removal of objectives and measures that no longer provide useful performance information, and is pleased that CMS has removed this objective for meaningful use in 2017 and subsequent years.**

In response to previous comments by CHA and other stakeholders, CMS proposes to reduce the thresholds of a subset of the remaining objectives and measures in Modified Stage 2 for 2017 and in Stage 3 for 2017 and 2018 for eligible hospitals and CAHs attesting under the Medicare EHR Incentive program. Specifically, for both Modified Stage 2 in 2017 and Stage 3 in 2018, CMS proposes to reduce the threshold for the View, Download, Transmit measure, in the Patient Electronic Access objective in Modified Stage 2, and the Coordination of Care Through Patient Engagement objective in Stage 3, from more than 5 percent in Modified Stage 2 and 10 percent in Stage 3 to **at least one patient.** CMS also proposes to reduce the threshold for the patient access measure in the Patient Electronic Access to Health Information objective from 80 percent to 50 percent. **While CHA appreciates that CMS has reduced these measure thresholds, we remain concerned about measures that hold the provider accountable for factors outside of their control.** Fully recognizing that some patients do not have regular access to the internet, and that some patients do not wish to view their health information online, hospitals are creating artificial mechanisms and processes during hospitalization and at discharge to ensure the measure is met without achieving the goal of patient and family engagement in care.

**We continue to strongly oppose requirements that hospitals ensure the patient’s health information is available on the application-program interface (API) of the patient’s choice.** We believe it is premature to require the use of APIs by providers because of the lack of standards maturity, the security risks they pose, and the significant policy questions that must be addressed. The use of APIs holds promise, but we lack evidence on the readiness of the approach in any clinical setting. As stakeholders continue developing standards and implementation specifications for APIs that could be used by EHR vendors, CHA urges CMS to evaluate provider experience with use and optimization of API functionality. **CHA urges CMS to delay requirements for use of API technology until such a study is conducted and the technology is mature enough to support evidence-based improvements to the exchange of health information.**

CHA also appreciates that CMS proposes to reduce Stage 3 thresholds for most objectives and measures to Modified Stage 2 thresholds. **CHA is pleased that CMS has responded to hospitals’ concerns that more time is needed for the systems to mature before thresholds are raised.** However, the exception is the electronic prescribing objective and measure, which would remain at 25 percent for Stage 3, and the patient generated health data measure which remains at more than 5 percent of all unique patients. CHA continues to believe that the threshold of 25 percent of hospital discharges will be a very difficult standard for many hospitals to reach, in part because many providers, including pharmacies,
outside the meaningful use program do not have EHRs. The threshold is especially challenging in low-income communities where safety net hospitals exist. Often, the patients these hospitals serve are not already connected to a pharmacy; many community pharmacies do not have electronic capability.

CHA believes any decision to increase the threshold should be based on past experience with the measure, and that CMS should wait to increase the threshold until an assessment of the experience to date can be completed. The proposed rule does not address why CMS believes a higher threshold for the measure is appropriate for Stage 3, while it reduces thresholds for the other measures. CHA urges CMS to maintain the Modified Stage 2 threshold of 10 percent for the electronic prescribing objective and measure in Stage 3 for 2017 and 2018.

CHA supports the exchange of patient data to ensure better coordination of care between providers, and agrees with CMS that widespread interoperable health information exchange remains challenging. However the current program structure, which includes providers who are not eligible to participate in the EHR Incentive program, makes even the Modified Stage 2 standard clinical information reconciliation measure threshold of greater than 50 percent of new encounters challenging for providers to achieve. Clinical information reconciliation is very complicated and continues to be mostly a manual process, as the tools to achieve clinical information reconciliation are not yet advanced enough to make it an intuitive process. CHA recommends the threshold be reduced further to 25 percent.

In addition, CMS proposes to require that all providers attesting to meaningful use for the first time in 2017 attest to Modified Stage 2 requirements, rather than allowing for attestation to Stage 3, as previously finalized. CHA supports this proposal.

CMS also proposes a one-time significant hardship exception for EPs who are new participants in the EHR Incentive program in 2017 and are transitioning to MIPS. CHA supports this proposal and appreciates CMS’ consideration for EPs transitioning to MIPS.

Finally, CMS proposes to change its policy on measure calculations for actions outside the EHR reporting period for the EHR Incentive program. Specifically, CMS proposes that, for all meaningful use measures, unless otherwise specified, actions included in the numerator must occur within the EHR reporting period if that period is a full calendar year, or if it is less than a full calendar year, within the calendar year in which the EHR reporting period occurs. CHA supports this proposal.

CHA appreciates the opportunity to comment on CMS’s proposals outlined in the proposed rule. If you have any questions, please contact me at akeefe@calhospital.org or (202) 488-4688.

Sincerely,

/s/
Alyssa Keefe
Vice President Federal Regulatory Affairs

Enclosure: OSHPD Flow Chart
CALIFORNIA MEDICAL CLINIC GUIDELINES FOR PLAN REVIEW, APPROVAL, INSPECTION AND CERTIFICATION

1. Is the building intended to be licensed by CDPH?
   - NO → Doctors’ Office
   - YES → Is the clinic under a CDPH hospital license?

2. Is the clinic under a CDPH hospital license?
   - NO → Local plan review, permit, inspection and approval to Title 24. Excludes OSHPD 3.
   - YES → Local plan review, permit, inspection and approval to Title 24. Excludes OSHPD 3.

3. Hospital Building (H&SC 1250)
   - OSHPD review and approval to Title 24 including OSHPD 1

4. Nonhospital Building Freestanding Clinic (H&SC 1250)
   - Owner selects plan review agency
   - OSHPD plan review, certify, permit, inspection and approval to Title 24 including OSHPD 3
   - Local plan review, permit, inspection and approval to Title 24 including OSHPD 3

5. Chronic Dialysis and Surgery Clinic (H&SC 1200)
   - Local plan review to Title 24 (except OSHPD 3). Local permit, inspection and approval to Title 24 including OSHPD 3

6. Rehabilitation Clinic and Alternate Birthing Center (H&SC 1200)
   - Local plan review, permit, inspection and approval to Title 24 including OSHPD 3

7. Licensed Freestanding Specialty Clinic (H&SC 1200)
   - OSHPD plan review and certify to Title 24 including OSHPD 3
   - Local plan review, permit, inspection and approval to Title 24 including OSHPD 3

8. Licensed Primary Care Clinic (includes Community, Free, Employee & Optometric clinics) and Psychology Clinic (H&SC 1200)
   - Local plan review, certify, permit, inspection and approval to Title 24 including OSHPD 3
   - CDPH conducts survey for Surgical and Dialysis Clinics only

9. Will local provide certification to OSHPD 3?
   - NO → OSHPD plan review and certify to OSHPD 3 only
   - YES → OSHPD plan review and certify to Title 24 including OSHPD 3

10. Local plan review to Title 24 (except OSHPD 3). Local permit, inspection and approval to Title 24 including OSHPD 3

11. Local plan review, permit, inspection and approval to Title 24 including OSHPD 3

12. Local plan review to Title 24 (except OSHPD 3). Local permit, inspection and approval to Title 24 including OSHPD 3

13. OSHPD accepts? (consult with local)
   - NO → Will local provide certification to OSHPD 3?
   - YES → OSHPD plan review and certify to Title 24 including OSHPD 3

14. Local plan review, permit, inspection and approval to Title 24 including OSHPD 3

15. Local plan review, certify, permit, inspection and approval to Title 24 including OSHPD 3

16. Local plan review, permit, inspection and approval to Title 24 including OSHPD 3

17. Local plan review to Title 24 (except OSHPD 3). Local permit, inspection and approval to Title 24 including OSHPD 3

18. Local plan review, permit, inspection and approval to Title 24 including OSHPD 3

19. Will local provide certification to OSHPD 3?
   - NO → Local plan review, permit, inspection and approval to Title 24 including OSHPD 3
   - YES → OSHPD plan review and certify to Title 24 including OSHPD 3

20. Local plan review, permit, inspection and approval to Title 24 including OSHPD 3

21. Local plan review to Title 24 (except OSHPD 3). Local permit, inspection and approval to Title 24 including OSHPD 3

22. Local plan review, certify, permit, inspection and approval to Title 24 including OSHPD 3


24. Local plan review, permit, inspection and approval to Title 24 including OSHPD 3

25. Local plan review, permit, inspection and approval to Title 24 including OSHPD 3

26. Local plan review, permit, inspection and approval to Title 24 including OSHPD 3

27. Local plan review, permit, inspection and approval to Title 24 including OSHPD 3

28. Doctors’ Office

29. ASC Certified for Medicare

30. Local plan review, permit, inspection and approval to Title 24. Excludes OSHPD 3.

NOTE: Compliance with Title 24, California Building Standards Code, including OSHPD 3 provisions, is required unless otherwise noted.

Revised 3/3/14

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