CALIFORNIA HOSPITAL ASSOCIATION

*Providing Leadership in Health Policy and Advocacy*

September 10, 2018

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, SW, Room 445-G
Washington, D.C. 20201

***SUBJECT: CMS–1693–P, Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; and Medicaid Promoting Interoperability Program Proposed Rule, Federal Register (Vol. 83, No. 145), July 27, 2018***

Dear Administrator Verma:

The California Hospital Association (CHA) appreciates the opportunity to submit comments on the Centers for Medicare & Medicaid Services' (CMS) proposed rule revising payment policies under the physician fee schedule (PFS) and Quality Payment Program (QPP) for calendar year (CY) 2019. CHA is committed to working with our physician partners to provide high-quality care while improving value and efficiency for the patients we serve.

**CHA is deeply disappointed that the agency continues to ignore the significant differences in regulatory requirements and responsibilities of the hospital outpatient department (HOPD) in providing health care services to Medicare beneficiaries. Continued expansion of site-neutral payment policies under the proposed PFS relativity adjuster methodology fundamentally undermines the Medicare payment systems. We urge CMS to prioritize refining this methodology, as we believe a more robust analysis would support a payment rate of 65 percent of the outpatient prospective payment system (OPPS) rates.**

CHA also provides comments on a number of the provisions of the proposed rule that are significant to hospitals and the physicians who provide care in our hospitals. In summary, CHA:

- Urges CMS to withdraw its proposal collapsing payment rates for evaluation and management (E/M) level 2 through 5 visits and engage stakeholders to address the flawed and outdated coding system to improve payment accuracy in the future. However, we urge CMS to finalize its proposals to reduce documentation burden.
- Supports CMS' proposals to pay for physicians' use of communication technology-based services, including virtual check-ins, store-and-forward evaluations, and interprofessional consultations.
- Strongly opposes CMS' proposal to reduce payments for separately payable Part B drugs from wholesale acquisition cost (WAC) plus 6 percent to WAC plus 3 percent.
- Urges CMS not to finalize its proposal to change the applicable laboratory definition. We also ask CMS to increase transparency under the clinical laboratory fee schedule (CLFS) payment

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system to address data integrity concerns and provide a transparent process that allows the data collected by CMS to be validated.
- Urges CMS to exempt hospitals from reporting appropriate use criteria (AUC) consultation on the facility claim, preserving limited agency resources to focus efforts on implementing appropriate collection of information on the professional service claim in the least burdensome manner possible.
- Supports the continued implementation of a facility-based reporting option for hospital-based clinicians under the Merit-based Incentive Payment System (MIPS).
- Does not support the creation of additional Medicare Conditions of Participation (CoPs) to require the electronic transfer of health information, and urges the agency to reject a piecemeal approach to CoP revisions that does not consider implications across the delivery system.

## Payment Rates Under the Medicare PFS for Nonexcepted Items and Services Furnished by Nonexcepted Off-Campus HOPDs

Section 603 of the Bipartisan Budget Act (BBA) of 2015 excludes from the definition of covered HOPD services "applicable items and services" furnished on or after January 1, 2017, by certain off-campus outpatient departments of a provider (generally those that did not furnish such services before November 2, 2015) and provides for payment for those services furnished by off-campus provider-based departments (PBDs) under a Part B payment system other than the hospital OPPS ("applicable payment system" under Part B). In previous rulemaking, CMS established a PFS relativity adjuster to determine payment rates at these facilities. In the CY 2018 PFS proposed rule, CMS adopted a PFS relativity adjuster of 40 percent.

CMS notes that the 2019 rate-setting cycle is the first for which CMS will have claims data under the policy. CMS makes several technical adjustments to the prior analysis used to develop the previous 50 and 40 percent relativity adjusters. Using new data, CMS proposes to continue the 40 percent relativity adjuster unchanged. The proposed rule further indicates that it is maintaining the same policies as 2018 related to supervision, beneficiary cost sharing, geographic payment adjustments and partial hospitalization services.

**The CY 2019 methodology for calculating the PFS relativity adjuster remains woefully inadequate and continues not to account for the significant differences in patient and service mix at various off-campus PBDs subject to this policy. Further, we are deeply concerned that CMS has used this flawed methodology and policy rationale to expand the policy as articulated in the OPPS proposed rule. We address those proposed policies under separate cover.**

**We remain deeply disappointed that the agency continues to ignore the significant differences in regulatory requirements and responsibilities of HOPDs in providing health care services to our most vulnerable Medicare beneficiaries. Continued expansion of this methodology fundamentally undermines the Medicare payment systems and will jeopardize patient access to care across the state of California, most notably in our rural areas**.

At a minimum, CMS should consider a number of changes to further refine this analysis to ensure payment adequacy. Specifically, CMS does not sufficiently address the differences in packaging of services between the OPPS and PFS. **CHA strongly urges CMS to revisit its methodology and to make it an agency priority. We believe a more robust analysis would demonstrate that an adequate payment**

**rate of 65 percent of the OPPS rates more accurately reflects costs of providing services, ensuring access is not limited or curtailed.**

In addition, this administration has provided significant leadership in identifying the costs associated with burdensome regulations. However, CMS fails to analyze the regulatory framework and clear differences in the site of service settings — for instance, off-campus HOPDs' role in providing access, particularly with respect to emergency preparedness and readiness.

In California, the cost differences between establishing a traditional medical office for a physician and an off-campus HOPD are significant. The Medicare CoPs are just one of the significant costs borne by hospitals and health systems, but they pale in comparison to the significant costs of meeting California's building code standards, particularly those related to seismic compliance. Off-campus provider-based HOPD sites are not established without careful thought and consideration. The crush of regulations has forced many independent community physicians to look to their hospital partners for assistance; if assistance is not available, they may decide to leave the community. In many cases, providers — particularly those in medically underserved communities — have no choice but to establish an HOPD, just to keep a physician in the community. **The costs health systems bear to maintain these off-campus HOPDs is significant. CMS' failure to recognize and account for these factors when developing a payment methodology is of great concern and we urge the agency to do additional work in this area.**

However, CHA supports CMS' continued policies that allow exceptions for relocation of nonexcepted off-campus PBDs and urges the agency to consider additional exceptions to address many events that are beyond a hospital's control. In addition, we support CMS continuing to allow regional office discretion in defining a "campus" and the inclusion of remote campuses in the current definition.

## Evaluation & Management Visits

In response to long-held stakeholder concerns over outdated and burdensome documentation guidelines from E/M services, CMS proposes a number of changes intended to reduce burden and improve payment accuracy. **CHA appreciates CMS' efforts to address the field's concerns through its previous comment solicitations, listening sessions and now in formal proposals through notice and comment rulemaking. However, CHA is deeply concerned that the proposed payment policies would result in unintended consequences that do not meet the stated agency and field goals of reducing administrative burden and providing the most efficient, high-quality care for beneficiaries.**

**We urge the agency to withdraw its proposal to pay a single, blended rate for levels 2 through 5 E/M visits. Moreover, we urge CMS to consider the comments submitted and engage stakeholders to discuss changes to the E/M coding and documentation requirements.** We disagree with the agency's assessment that eliminating the distinction in payment between these visit levels will provide immediate documentation burden relief and eliminate the need for auditing based on the level of visit billed. Rather, in practice, the documentation burden will largely remain, and payment cuts for the most clinically complex patient visits will limit access for Medicare beneficiaries. Further, the additional payment proposals will introduce additional complexity to the system.

We are disappointed that CMS has not made readily available the data necessary to fully analyze this policy, missing an opportunity for more meaningful input. Rather, we have had to rely on CHA member hospitals' attempts to model these impacts, which is a significant challenge and does not allow for robust statewide analysis. We also note that other stakeholders — including the American Medical

Association and Association of American Medical Colleges — have been unable to replicate the analysis provided by CMS, finding much more significant impacts to specialists who serve the most complex patients. Going forward, we urge the agency to make available more transparent and robust data so that stakeholders can fully understand the impacts of the agency's proposals.

A common concern expressed by our rural hospitals is the impact this payment proposal may have on access to specialist services in their communities. Rural communities struggle to retain specialists in their area and, with a shortage of clinical personnel challenging so many of our hospitals, it is critically important that Medicare payment be adequate to maintain these services in even the most remote locations. In addition, a number of our large urban and academic medical systems express significant concern. Specialty physicians at these hospitals often care for some of the sickest, most clinically complex patients. The proposed payment cuts may jeopardize access to care.

CHA shares the concerns expressed by some stakeholders that such a payment proposal would incentivize higher frequency visits so that providers are able to recoup the financial losses from level 4 and 5 visits. More concerning, this policy could have the unintended consequence of requiring patients to have to return more often to the physician office, creating inefficiencies and reducing value for patients, providers and the Medicare program.

CMS proposes to allow practitioners to use 1995 or 1997 guidelines, medical decision making (MDM) or time to determine the appropriate level of E/M visit. CMS also proposes – for the purposes of PFS payment for an office or outpatient E/M visit – that practitioners would only need to meet documentation requirements currently associated with a level 2 visit for history, exam or MDM (except when using time to document the service). However, in the proposed rule, CMS notes "practitioners could choose to document more information for clinical, legal, operational or other purposes, and we anticipate that for those reasons, they would continue generally to seek to document medical record information that is consistent with the level of care furnished." CHA believes this is a likely scenario, as current documentation guidelines are built into hospital and health system electronic medical record system workflows and will, for the foreseeable future, continue to be used for other commercial payers and for risk adjustment in numerous types of alternative payment models (APMs) and other contracting arrangements. **CHA urges CMS to further engage stakeholders to address the currently flawed and outdated coding system to improve payment accuracy, rather than reducing documentation requirements to levels that do not reflect the work intensity inherent in more complex E/M visits.**

CMS further complicates the current payment system by proposing to pay for add-on codes to reflect the additional resources inherent in providing primary care services, for visit complexity in non-procedural services for certain specialties and for prolonged visits. Rather than complicate the payment system with new G-codes, we urge the agency to work with stakeholders to identify opportunities to improve and simplify coding for payment accuracy. Further, the proposed rule does not clearly state the documentation requirements that will be needed to justify payment for such an add-on code. **We urge the agency to withdraw its payment proposals and instead take a more holistic approach in updating the coding system and documentation guidelines.**

However, we do believe some of the agency's proposals would be successful in reducing burden; these can — and should — be separated from its payment proposals. Specifically, CMS proposes to reduce redundancy in E/M visit documentation by proposing that, for established patients, providers be required to document only what has changed since the last visit or pertinent items that have not

changed, rather than re-documenting a defined list of required elements. CMS also proposes, for both new and established patients, that providers no longer be required to re-enter in the medical record information related to patients' chief complaint and history, if that information was already entered by ancillary staff or the beneficiary. **CHA supports these proposals and agrees that they will reduce administrative burden. CHA urges CMS to finalize these specific documentation proposals separate from the payment reduction proposal.**

CMS proposes to remove the requirement that the medical record document the medical necessity of furnishing the visit in the home rather than in the office, because it is unnecessary. **CHA agrees that physicians are in the best position to determine where the patient should be seen and supports this proposal.**

CMS also proposes to eliminate the prohibition on billing for same-day E/M visits by a physician, or physician of the same specialty from the same group practice, for the same beneficiary on the same day. CHA has long supported the elimination of this prohibition, as same-day visits are often the most convenient and clinically appropriate option for the patient. **This proposal is especially helpful for patients in rural communities who must travel for their appointments, as well as for complex patients who may need to see multiple physicians within the same practice on the same day. CHA strongly supports this proposal.**

## Modernizing Medicare Physician Payment by Recognizing Communication Technology-Based Services and Expanding Telehealth Services

Current law defines Medicare telehealth services and specifies the payment amounts and circumstances under which Medicare makes payment for a discrete set of services, all of which must ordinarily be furnished in-person, when they are instead furnished using interactive, real-time telecommunications technology. In the proposed rule, CMS states that it has come to believe the law does not apply to all kinds of physicians' services whereby a medical professional interacts with a patient via remote communication technology. **Many California hospitals are at the forefront of new delivering care using new technologies and CHA is pleased to see the agency is taking a forward-looking approach to the delivery of health care, especially in this rapidly changing technology environment.**

For CY 2019, CMS proposes to recognize a discrete set of services that are defined by and inherently involve the use of communication technology. CMS notes that it believes these proposals would not be subject to the limitations on Medicare telehealth services under current law. **CHA agrees with this interpretation of the law and appreciates that CMS is taking steps to recognize the way care is delivered using new communication technologies.**

CMS proposes a new billable service for a "virtual check-in," when a physician or other qualified health care professional has a brief non-face-to-face check-in with a patient via communication technology to assess whether the patient's condition necessitates an office visit. The proposed code would be payable only when it does not originate from a related E/M service provided within the previous seven days or lead to an E/M service or procedure within the next 24 hours or soonest available appointment. In those situations, the check-in service would be bundled with the relevant E/M visit. **CHA strongly supports this proposal. The proposed code and corresponding payment would recognize the important service provided by a clinician, which could prevent unnecessary office visits while still addressing the beneficiary's needs. Paying physicians for time spent effectively managing a patient is particularly important under an APM in which coordinated care of the beneficiary is a key factor in managing the**

**total cost of an episode. Moreover, the opportunity for beneficiaries to actively engage with their physicians in the management of their care outside of the office setting will also likely lead to higher patient satisfaction. While we support this proposal and are encouraged by the agency's move in this direction, we worry that CMS has not sufficiently valued this service to encourage participation outside an APM or risk-sharing arrangement. We urge CMS to consider increased payment for this code in the future to further promote its use in both fee-for-service and APMs.**

Similarly, CMS proposes a billable code for a service under which a provider evaluates a patient-generated still or video image and subsequent communication of his or her professional opinion to the patient. Like the "virtual check-in," the service would only be billable separately from a prior or subsequent E/M visit. **CHA strongly supports this proposal and believes both newly proposed services will be valuable to clinicians and beneficiaries in improving access to and coordination of care.**

**In addition, CHA supports CMS' proposal about separate payment for six current procedural terminology codes that relate to interprofessional telephone/internet assessment and management service provided by a consultative physician**. Currently, the resource costs associated with seeking or providing such a consultation are bundled, which provides an incentive for the specialist to schedule a separate visit for the patient when a phone or internet-based interaction with the consulting practitioner would have sufficed. This policy increases efficiencies for physicians and patients.

**Communication Technology-Based Services in Rural Health Clinics and Federally Qualified Health Centers**

Patients in rural communities and areas with a shortage of health professionals face significant barriers to accessing care. The use of new technologies to more efficiently deliver care will greatly benefit these populations. These technologies offer convenience to patients who must travel great distances to receive care and will help alleviate workforce shortages in rural communities. **CHA is extremely supportive of CMS' proposals to pay for communication technology-based services or remote evaluation services furnished by practitioners at rural health clinics or federally qualified health centers to patients who have been seen in the facility within the previous year.**

**Medicare Telehealth Services**

CHA supports CMS' proposal to add two services to the list of Medicare-payable telehealth services, both related to prolonged preventive services beyond the typical service time of the primary procedure; Healthcare Common Procedure Coding System (HCPCS) code G0513 is the first 30 minutes, and G0514 is each additional 30 minutes. **We urge CMS to continue evaluating services for payment under telehealth and further expand Medicare telehealth services to improve access to care where the shortage of clinicians in many areas across the state, especially our rural areas, is felt most prominently. Further, we ask that the agency work with Congress to expand Medicare coverage of telehealth services by presuming that Medicare-covered services also are covered when delivered via telehealth, unless CMS determines — on a case-by-case basis — that such coverage is inappropriate.** This presumption will facilitate increased use of this important technology, resulting in better patient care and increased efficiency.

## Therapy Services

**Proposed Functional Reporting Modifications**

In response to stakeholder concerns that functional reporting requirements are overly complex and burdensome, CMS proposes to discontinue the functional reporting requirements for therapy services

furnished on or after January 1, 2019. Accordingly, with the conclusion of the functional reporting system for dates of service after December 31, 2018, CMS plans to eliminate the applicable regulations that require functional reporting as a condition of payment, make the relevant claims processing systems edits to no longer require functional reporting and delete the applicable non-payable HCPCS G-codes specifically developed to implement functional reporting. We appreciate Congress' and CMS' recognition of the ongoing changes in payment policy for outpatient therapy services, most notably the elimination of the statutory therapy caps. Moreover, we applaud CMS' efforts to reassess the value of the current reporting requirements and data collection, and to make changes that will reduce administrative burden. **CHA strongly supports this proposal.**

**Proposed Payment for Outpatient PT and OT Services Furnished by Therapy Assistants**
The BBA of 2018 also included a provision reducing payment to therapy services furnished in whole or part by a physical therapy (PT) or occupational therapy (OT) assistant to 85 percent of the PFS amount beginning January 1, 2022. CMS proposes two new therapy modifiers to identify these services, rather than the current GP and GO modifiers. Effective for dates of service on and after January 1, 2020, five therapy modifiers would be used to track outpatient therapy services instead of the current three. The new therapy modifiers would be required to be used whenever a PT or OT assistant furnishes all or part of any covered outpatient therapy service.

CMS anticipates allowing voluntary reporting of the new modifiers at some point during 2019, which it will announce to contractors and therapy providers through a Change Request, as part of the usual change management process. **CHA supports the implementation of a voluntary period for reporting prior to implementation in CY 2020, and urges CMS to provide adequate information and resources for providers to limit unnecessary billing and payment errors.**

## Part B Drugs: Application of an Add-on Percentage for Certain Wholesale Acquisition Cost-Based Payments

Many Part B drug payments are based on the average sales price (ASP) methodology and, by statute, include an add-on payment of 6 percent of the ASP amount. Some Part B drugs are based on WAC, such as single-source drugs without ASP data. The add-on percentage for drug payments is typically applied to the ASP; in certain situations, the same 6 percent add-on is also applied to the WAC for Part B drug payments.

CMS notes that the Medicare Payment Advisory Commission (MedPAC) and others, including the Office of the Assistant Secretary for Planning and Evaluation (ASPE) and the Office of Inspector General, have raised concerns about the use of a 6 percent add-on payment for both ASP and WAC, which may create an incentive to use them. The June 2017 MedPAC report to Congress included a recommendation to reduce WAC-based payment to WAC plus 3 percent.

In response to those concerns, CMS proposes that, effective January 1, 2019, WAC-based payments for Part B drugs utilize a 3 percent add-on payment in place of the 6 percent add-on payment that is currently applied. CMS notes this proposal does not include WAC-based payments for single-source drugs under the provision of the statute that specifies that the payment is 106 percent of the lesser of ASP or WAC. In addition, this proposed policy would not alter the OPPS payment limit (95 percent of the published average wholesale price). **CHA strongly opposes this proposal for several reasons and believes it is nothing more than a blunt instrument to cut critically important payments to providers, rather than taking the necessary steps to fundamentally address the rising cost of prescription drugs.**

MedPAC's recommendations, which CMS cited in its rationale for this proposal, were part of a larger set of sequential steps the agency and Congress should consider in the future; they were not intended to be a standalone solution.

**First, the proposed reduction in payment ignores the current sequestration cut of 2 percent on separately payable Part B drugs. This cut effectively reduces current payments to WAC plus 4 percent, not WAC plus 6 percent. Further reduction in payment is unwarranted when the agency has not yet taken steps to address the lack of accurate and reliable ASP data. Due in part to this lack of data, CMS has no choice but to base payment on a drug's WAC — which MedPAC notes is a potentially inflated measure of price.**

More specifically, MedPAC notes in the June 2017 report that CMS should take immediate action to improve the ASP system in 2018 by requiring all manufacturers of products paid under Part B to submit ASP data; MedPAC also recommends penalties for those that fail to report. MedPAC notes that not all manufacturers are required to report ASP data. Therefore, those without Medicaid rebate agreements with states are exempt from reporting. This is a long-standing issue and one that CMS should address before setting forth additional proposals to decrease provider payments to providers.

In addition, CMS has taken no action to date to ensure the currently reported data are reliable and valid. The MedPAC analysis demonstrates the decrease in ASP over time, from quarter to quarter, but — because of the lag in data reporting — those decreases are not reflected in a timely fashion, which leads to inaccurate payments. CMS should take action to create a more timely and robust reporting system. ASP can change quickly; the data would be greatly improved by increasing reporting requirements for manufacturers, shortening the reporting time frames to account for the delay, and increasing oversight and analysis to ensure accurate reporting. While CMS notes its proposal does not include WAC-based payments for single-source drugs under the provision of the statute that specifies that the payment is 106 percent of the lesser of ASP or WAC, improving the data would only further improve payment accuracy.

CHA shares the administration's concerns that addressing the cost of prescription drugs is a top priority. However, the current proposals do nothing to address the root causes of rising drug prices. We ask CMS to withdraw this policy and work with stakeholders to develop more robust solutions that address the issue's foundation.

## Clinical Laboratory Fee Schedule

CMS notes that, under the Protecting Access to Medicare Act of 2014 requirements, 2018 CLFS payment rates are based on reporting from a relatively small number of laboratories and do not include payment rates for most hospital-based laboratories. While we recognize that CMS believes the law was intended to exclude most hospitals from reporting, CHA has long expressed concerns that the lack of hospital payment data in the reporting inaccurately reflects the private payer market under which the CLFS payment rates are now based, resulting in substantially decreased reimbursement. We appreciate that CMS continues to seek opportunities to expand reporting that will achieve a balance between collecting sufficient data to reflect the private market rate while minimizing the reporting burden for entities; however, we believe the current proposals fall short of this goal.

**Proposed Changes to Applicable Laboratory Definition**
CMS proposes to remove payments from Medicare Advantage (MA) plans from the denominator of the fraction that is used to determine whether a laboratory received more than 50 percent of its revenues from physician fee schedule and CLFS services. CMS notes that its proposed policy of considering MA plan revenues as private payer payments would only be applicable for this provision and will have no bearing on how CMS considers MA plan payments in other contexts.

CMS believes that excluding MA plan revenues from total Medicare revenues will result in more laboratories of all types meeting the majority of Medicare revenues threshold and reporting private payer rates. However, CHA is unable to analyze how this proposal would impact hospital-based laboratories due to a lack of available data for meaningful analysis. Further, while CMS states that it estimates this proposal would increase the number of applicable laboratories by 835, it does not provide any information related to the identification of these labs or their potential impact on payment rates. **CHA urges CMS to conduct a more robust and transparent analysis that includes the types of applicable laboratories to which this policy would apply, as well as the relative impact on payment rates. As a first step, we urge the agency to release, as soon as possible, the number of clinical laboratories that previously reported private payer data, based on market segment and geographic locations. While CMS notes that this proposal is expected to have a minimal impact on CLFS rates, there is relatively little information for stakeholders to make informed comments on the reliability or validity of such statements. Therefore, without additional information, we believe it is premature for CMS to implement a proposal that will only increase administrative burden on hospitals and other organizations, which will be forced to redetermine their applicability for reporting status. While we appreciate the agency's attempt to address stakeholder concerns, CHA does not support this proposal going forward.**

Further, we continue to have serious concerns that the data CMS collected from laboratories in its first data collection period were inaccurate, incomplete and unable to be validated — resulting in payment rates that did not accurately reflect the broad spectrum of private payer payment rates as Congress intended. **As CMS prepares for the 2019 data collection period, the agency must take steps to improve and simplify the data collection and reporting process, including addressing data integrity concerns through a statistically valid process that is least burdensome on providers and providing a transparent process to allow data collected by CMS to be validated.**

**Requests for Comment on Alternative Approaches**
CMS seeks public comment on alternative approaches suggested by stakeholders for defining an "applicable laboratory," even though some of these suggestions were previously considered and rejected in prior rulemaking. These include using Form CMS-1450 bill type 14x to determine a majority of Medicare revenues and low expenditure thresholds, or using the Clinical Laboratory Improvement Amendments (CLIA) certificate to define applicable laboratories. **CHA generally agrees with the concerns laid out by CMS and would not support the use of either approach, explained in more detail below.**

*Form CMS-1450 bill type 14x*: The 14x bill type, used only by hospital outreach laboratories, is a billing mechanism that is currently used only for a limited set of services. CMS notes that private payers, such as MA plans, may not require hospital laboratories to use the 14x bill type for their outreach laboratory services and that hospitals would likely need to develop their own mechanism for identifying and reporting only the applicable information associated with its hospital outreach laboratory services. This

would increase the burden on hospitals substantially. Further, CMS notes that, should this approach be utilized, hospitals would need sufficient time to develop and implement the information systems necessary to collect private payer rate data before the start of the next data collection period, which is January 1, 2019. Because CMS has not made a formal proposal and would need to engage in a rulemaking process and release necessary subregulatory guidance, there is absolutely not sufficient time to implement such a requirement by January 1, 2019. **CHA is strongly opposed to this approach.**

*CLIA Certificate:* CMS notes that some stakeholders have requested using the CLIA certificate, rather than the National Provider Identifier, to identify facilities that would be considered applicable laboratories. We agree with the agency that, because the CLIA certificate is not associated with Medicare billing, it is unclear how the certificate could be used to help a hospital determine whether its laboratories meet the majority of Medicare revenues thresholds or the low-expenditure threshold. This approach would create undue burden on hospitals in determining their status as an applicable laboratory. **CHA is strongly opposed to this approach.**

**Changes to the Low-Expenditure Threshold**
CMS notes it is considering changes to the low-expenditure threshold and seeks public comment on whether it should do so. In response to stakeholders who wish to increase the number of applicable laboratories, CMS considers decreasing the low-expenditure threshold to $6,250, which would be likely to increase the level of participation among physician office laboratories and small independent laboratories. Alternatively, to reduce reporting burden on those physician office and small independent laboratories, CMS seeks comments on increasing the low-expenditure threshold to $18,750. **At this time, CHA does not support any changes to the low-expenditure threshold. We encourage the agency to allow the program to mature and to only make changes after a careful and transparent review of the data, with additional opportunities for public comment.**

## Appropriate Use Criteria for Advanced Diagnostic Imaging Services

As required by the Protecting Access to Medicare Act of 2014, CMS continues to implement a program to promote the use of AUC for advanced diagnostic imaging services. CMS proposes a number of changes, including an expansion of applicable settings, establishment of a claims-based reporting mechanism, modifications to hardship exceptions and refinement of regulatory language to better reflect statutory requirements.

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. We believe that successful implementation of such a significant program requires appropriate lead time to make necessary investments in technology, adjustments to workflow and changes within billing departments. **While we appreciate that CMS has taken a thoughtful approach to program implementation with a delayed start date of January 1, 2020, we continue to have concerns about the operational challenges this program will pose for hospitals. We urge the agency to withdraw its proposal to require AUC consultation information on the facility claim.**

CMS proposes to revise its regulations to clarify that AUC consultation information must be reported on all claims paid under applicable payment systems, without exclusion. CMS believes that the statute requires AUC consultation information on both the furnishing practitioner's claim for the professional component and the provider's or supplier's claim for the facility portion or technical component of the

imaging service. However, the law does not explicitly require facilities to report this information for the technical component.

More importantly, there is no way for hospitals to report the ordering physician associated with an advanced imaging procedure on the electronic standard billing form for institutional claims (837I). **While there are fields available to report the attending and operating physician, as well as two "other" physician fields, none of these fields is tied to the actual procedures performed**. In addition, there could be multiple procedures performed during one outpatient visit (e.g., surgery and advanced imaging), meaning there could be multiple physicians involved in the care being provided. This inability to tie physician fields to the procedures performed on the facility claim will prevent the agency from tying the ordering professional to the imaging service; therefore, CMS will be unable to achieve the program's goal of appropriately identifying outlier ordering physicians.

CHA strongly believes AUC consultation information provided on the professional service claim is sufficient for CMS to identify outliers. It would be duplicative for hospitals to report this information on the facility claim, increasing burden both for facilities in reporting and for the agency in analyzing claims. **Therefore, CHA urges CMS to exempt hospitals from reporting the AUC consultation on the facility claim.** Rather, limited agency resources should focus on efforts to further refine the information collected on the professional service claim and begin to develop and make transparent the protocols and framework for identifying outliers.

**Claims-Based Reporting**

Should CMS disagree and finalize its proposed approach, we offer a number of considerations related to claims-based reporting. In the 2018 PFS proposed rule, CMS proposed to establish a series of G-codes and HCPCS modifiers to capture AUC consultation information on Medicare claims. As discussed in the 2018 PFS final rule, CMS received numerous public comments objecting to this proposal. Many commenters suggested using a unique consultation identifier (UCI) instead of using combinations of G-codes and modifiers. However, CMS has since determined that the use of a UCI would present a number of challenges, and once again proposes to use established coding methods that include G-codes and modifiers to report the required AUC information on Medicare claims.

If hospitals must report the information on the clinical decision support mechanism (CDSM) consulted, we agree that the G-code is a better option than the previously considered UCI. That said, we have concerns surrounding how this information will accurately flow through the claim submission process. Claims experts have identified a concerning issue with reporting a separate service line for the HCPCS G-Code. Often, during claims processing, the service lines are re-ordered by billing systems or clearinghouses based on claims adjudication rules; this could result in the procedure service line and AUC service line being separated. For a claim with multiple procedures and multiple related HCPCS G-codes, it would be difficult to determine during data analysis which service lines were tied together. As a result, it would be difficult — or impossible — to determine which physician ordered the advanced imaging procedure, presenting a challenge for identifying outlier professionals.

**Further, while we support CMS' proposal to treat the first year of implementation as an educational and operational testing period, we urge the agency to delay the mandatory reporting period until the specific details of reporting this information on the claim are known.** The CY 2018 PFS final rule established a voluntary reporting period from July 2018 through December 2019. The HCPCS modifier QQ was created to indicate that the ordering professional consulted the CDSM for the service, and the

related information was provided to the furnishing professional. Due to the complexity of the AUC program and the lack of an established method at this time for reporting the AUC data in the claim, providers and their software and billing system partners will need additional time to prepare to report any new codes. The technical components involved in this AUC program will require systems and operation changes for providers, Medicare administrative contractors and other involved payers. It will be critical to test the system changes to confirm the technical aspects are functioning properly within and between all impacted organizations. These changes to billing systems are on top of significant investments required to ensure that CDSM mechanisms or modules are incorporated properly into workflow and, ideally, seamlessly integrated into certified electronic health record technology to support the delivery of high-quality care. We urge the agency not to underestimate the time such significant changes will require before implementing requirements that impact payment. **We urge CMS to allow voluntary reporting beyond December 31, 2019. In addition, we ask that CMS evaluate and make transparent the data and learnings from the voluntary reporting efforts so that additional stakeholder feedback can be solicited through notice and comment rulemaking as this program continues to roll out.**

Finally, we continue to be concerned that the AUC program required by law imposes regulatory requirements that require action by ordering professionals — but imposes payment consequences for hospitals if a professional fails to meet his or her requirements. While we agree that the hospital and health system have a role to play in support of our clinicians in making informed, evidence-based clinical decisions through the use of clinical support tools, **we urge CMS to consider additional ways to hold ordering physicians accountable if they fail to consult the readily available AUC before ordering imaging, rather than requiring reporting by the furnishing professional.** This may include a yearly attestation by ordering professionals that they have access to and consult CDSMs. At a minimum, we urge the agency to include clear instructions in the final rule and in the Medicare manuals that the ordering professional needs to include the necessary information when documenting their orders.

## Physician Self-Referral Law

CMS proposes a number of revisions to its regulations on the physician self-referral law, also known as the Stark Law, to reflect changes codified in the BBA of 2018. CHA appreciates that CMS and Congress have shown interest in improving the Stark Law and reducing the regulatory burden and costs it imposes on the nation's health care system. This interest was demonstrated in CMS' recent request for information seeking input on addressing undue regulatory impact and burden of the physician self-referral law, with a focus on how the law may impede care coordination. As noted in our response to that request, CHA supports a more holistic, aggressive approach to address the challenges. We recommend wiping the slate clean and developing a new statutory and regulatory framework that creates fewer barriers to the delivery and payment models that facilitate care coordination. We urge the agency and Congress to review recommendations and work together on the legislative and regulatory actions necessary to effectively address these issues.

## 2019 Updates to the Merit-Based Incentive Payment Program Under the Quality Payment Program

CHA appreciates CMS' ongoing efforts to engage with a wide range of stakeholders in understanding the challenges clinicians face in transitioning to participation in the Merit-Based Incentive Payment System (MIPS). We applaud CMS and Congress recognizing the need for additional flexibility in the program's third year and support a number of the incremental steps CMS takes toward implementation in this

proposed rule. We also support CMS' proposed changes intended to reduce burden and increase alignment between hospitals and clinicians. However, we offer of the following comments for CMS to consider in improving the program.

**MIPS Low-Volume Threshold**

CMS proposes to continue an incremental approach to increasing participation in MIPS for small and rural practices by largely maintaining the low-volume threshold finalized for CY 2018. CHA remains concerned about the impact of exempting such a large portion of Medicare payment from the MIPS requirements. As the health care system moves from volume to value, it is important that smaller practices — particularly those operating in our rural areas — receive assistance and education in achieving the goals of value-based care, rather than be excluded completely. **As we move forward in this program, CHA urges CMS to fully evaluate and make transparent the effects of its low-volume threshold on both those included and excluded from MIPS, and to work closely with stakeholders in determining additional MIPS participation opportunities in the future.**

**CHA supports allowing all low-volume clinicians who are ready and willing to participate in MIPS to opt in to the program, and we urge the agency to extend that opportunity to any clinician.** Instead, CMS proposes that only clinicians who meet or exceed one or two of the MIPS low-volume threshold criteria would be permitted to opt-in to MIPS participation, leaving those who do not meet or exceed any of the thresholds unable to opt-in should they wish to participate. Given that CMS would give clinicians who opt-in the option to either participate in MIPS voluntarily and not be subject to the MIPS adjustment, or fully participate in MIPS with a positive or negative MIPS adjustment depending on their performance, this could offer an important step for small practice and rural clinicians who are ready to test their ability to gather and submit performance data. **Finally, CMS does not specify in the proposed rule a deadline for opting into MIPS for a particular performance year. We urge the agency to clarify this deadline in the final rule.**

**MIPS Performance Period**

CMS proposes to retain the same performance period lengths it adopted in the CY 2018 QPP final rule. That is, CMS would require clinicians to report a full 12 months of quality data and use 12 months of claims data for the cost category. However, CMS would retain a reporting period of any continuous 90 days for the improvement activity and promoting interoperability categories. **CHA strongly supports the proposed performance period of 90 continuous days for the promoting interoperability and improvement activities performance categories. This is particularly important for the promoting interoperability performance category as clinicians transition to 2015 edition CEHRT in 2019. However, we urge CMS to consider a 90-day performance period across all four categories to further simplify the program.**

**MIPS Performance Categories**

*Quality*

For CY 2019 quality reporting, CMS generally proposes to maintain CY 2018 reporting requirements. In addition, consistent with its Meaningful Measures Initiative, CMS proposes to remove 34 measures from the CY 2019 MIPS measure set. The measures would be retired for being low-value or low-priority for improvement. **CHA applauds the agency for its efforts to reduce the reporting burden on clinicians and hospitals. We have long advocated for a more meaningful, parsimonious measure set that provides hospitals with clinically important information for performance improvement. We urge the agency to**

**continue to review its quality measure sets to identify the most meaningful measures, and we encourage further alignment between hospital and clinician reporting requirements.**

However, we urge the agency to reconsider its timeline for removing electronic clinical quality measures (eCQMs) from the measure set. CMS recently finalized changes to the measure set for hospitals under the Inpatient Quality Reporting Program, including the removal of seven eCQMs. Recognizing the significant resources expended in preparing to report selected eCQMs, CMS did not finalize the removal of these eCQMs until the 2020 reporting year. We urge the agency to follow suit in phasing out eCQMs over time for physicians, rather than removing these measures in the 2019 performance period. More specifically, we ask that CMS clearly define a transition period to limit the volatility this may present for the clinicians who have traditionally reported and relied on these measures.

*Cost*

Under the previous statute, CMS would have been required to raise the weight of the cost category to 30 percent by CY 2021. The BBA of 2018 amended the law so that CMS may apply a weight of no less than 10 percent though CY 2023. CMS proposes to gradually increase the weight of the MIPS cost category by 5 percent each year until it reaches 30 percent for CY 2024. Under this proposal, the weight of the category would increase from 10 to 15 percent for CY 2021. **We urge CMS to maintain the current category weight of 10 percent, as allowed under current law, for performance year 2019 and to evaluate the appropriate weight for each future performance period through notice and comment rulemaking.** CHA continues to be concerned with the CMS-developed cost measures in the QPP, discussed in more detail below. We oppose increasing the weight of the category until clinicians have more experience with these newly developed measures.

CMS proposes to continue to score clinicians and groups on two overall cost measures — Medicare spending per beneficiary (MSPB) and total cost per capita — that it finalized in the CY 2017 QPP final rule. In addition, beginning with the 2019 performance period/2021 payment year, CMS proposes to add eight episode-based measures. **CHA does not support the addition of eight additional episode-based cost measures at this time. We continue to have significant concerns with the lack of clinician experience with episode-based measures, overlap with the MSPB measure and the lack of risk adjustment for sociodemographic status. Should CMS proceed to increase the weight of the cost category from 10 to 15 percent for CY 2021, we strongly urge the agency *not* to add the additional eight episode-based measures at this time. More time is needed to refine the measures before their implementation into this program.**

**For example, CHA strongly urges the robust use of risk adjustment — including adjustment for sociodemographic status, where appropriate — to ensure providers do not perform poorly on cost measures simply because they care for more complex patients.** 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 these measures. For example, a January 2016 report issued by the National Academy of Medicine found evidence that a wide variety of social risk factors may influence performance on many types of health care outcome measures, such as readmissions, costs and patient experience of care.

In addition, the Improving Medicare Post-Acute Care Transformation Act required the Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation to conduct a study of risk adjustment for sociodemographic status on quality and resource use measures, and to

incorporate them as feasible and appropriate through future rulemaking. This report demonstrates that clinicians, hospitals and post-acute providers alike are more likely to score worse on CMS pay-for-performance programs when they care for large numbers of poor patients. **CMS should take these findings into consideration and provide additional data and analysis to the field to promote shared understanding of the measures and their impact to provider performance in the program.** Notably, the proposed episode-based measures are not endorsed by the National Quality Forum (NQF). The Measures Application Partnership (MAP) reviewed the measures in 2017, and conditionally supported them for inclusion in the QPP if they achieved NQF endorsement. Members of the MAP raised a number of concerns about risk adjustment and attribution that CMS has not yet fully addressed.

*Promoting Interoperability*

To better reflect the agency's focus on interoperability and improving patient access to health information, CMS renamed the Advancing Care Information performance category the Promoting Interoperability (PI) performance category. In addition, CMS proposes significant changes to the category's scoring methodology, which generally align with proposals recently finalized for hospitals under the Medicare and Medicaid Promoting Interoperability programs.

CHA appreciates CMS' stakeholder outreach in its efforts to better understand the challenges hospitals and clinicians face under the current electronic health record (EHR) reporting requirements. We also share CMS' goal of focusing on interoperability to ensure meaningful exchange of health information that supports improved quality of care for our patients. While we recognize the important steps CMS proposes to increase flexibility and reduce burden on providers, we offer a number of additional comments that support improved use of EHRs throughout the health care continuum. We previously provided comments on the similar policies proposed for hospitals in the FFY 2019 inpatient prospective payment system (IPPS) proposed rule.

Proposed Changes to Scoring Methodology

Similar to changes recently finalized for hospitals, CMS proposes a new performance-based scoring methodology for the category, under which clinicians would receive scores for each required measure, except for those that require a "yes or no" submission. The performance rate of the individual measure would then be multiplied by the maximum points available for a particular measure. **CHA supports the proposed scoring methodology and recommends that CMS establish a threshold of a minimum of 50 points to meet the measure scoring requirements for the Promoting Interoperability performance category. A 50-point threshold would align with the scoring methodology minimum requirement for hospitals in the Promoting Interoperability program, as finalized in the FFY 2019 IPPS final rule.**

Certification Requirements

While we recognize many hospitals are prepared to transition to 2015 Edition CEHRT in 2019, we are concerned with the ability of our physician partners — especially those who provide care in small and rural hospitals — to transition by 2019. **We urge CMS to explore additional flexibilities that will allow small, rural hospitals, critical access hospitals and their physician partners to continue to advance efforts to electronically share information. We also ask CMS to further consider limiting payment penalties or granting additional hardship exemptions for these uniquely burdened and financially challenged hospitals and providers.**

Provider to Patient Exchange Objective

We continue to have concerns about the readiness of hospitals and clinicians to report on the single measure in the Provider to Patient Exchange objective — Provide Patient Electronic Access to Their Health Information. While CHA strongly supports providing patients with access to their health information, we continue to have significant concerns with the requirements to provide the information through the application of a patient's choice. **California hospitals report that it has been difficult, if not impossible, for EHR vendors to implement workflow upgrades and other changing requirements in a timely way to ensure providers can meet these requirements. Despite 2015 Edition CEHRT requirements, hospitals continue to report a lack of available application programming interfaces (API) from vendors. CMS should not continue to mandate requirements that are not supported by the agency's certification criteria and enforcement of that certification. Doing so puts providers at significant risk of financial penalty.**

We appreciate that CMS clarified in the FFY 2019 IPPS final rule that each application should be registered and identifiable so the health care provider or the vendor that supplies the API technology can deactivate any application's access if it functions in anomalous or malicious ways. **We continue to urge the agency to work with the Office of the National Coordinator for Health Information Technology to develop a standardized approval and oversight framework specific to patient-directed health applications.**

ePrescribing Objective

**CMS should retain both newly proposed measures under the ePrescribing objective as optional and available for bonus point scoring for 2020.** We appreciate that, in the FFY 2019 IPPS final rule, CMS finalized the Verify Opioid Treatment Agreement measure as optional for both 2019 and 2020 under the hospital Promoting Interoperability programs, and urge the agency to align clinician reporting requirements.

We agree that consultation of a prescription drug monitoring program (PDMP) is important for tracking prescribed controlled substances; however, the technology to integrate this process into the EHR is still under development. California's PDMP is moving toward an electronic interface with hospital and provider EHRs, as required by state law. However, to date, the state has not developed or implemented the needed API, making it impossible for California hospitals to meet this measure without manually entering data into the CEHRT. **The administrative burden and financial resources required — absent technology to assist — do not align with the agency's goals of streamlining and simplifying this program. Therefore, CHA urges CMS to retain the measure as optional in 2020 and make it available for bonus point scoring.**

Public Health and Clinical Data Exchange Objective

We also appreciate that CMS finalized increased flexibility for hospitals under the Public Health and Clinical Data Exchange objective in the FFY 2019 IPPS final rule by allowing hospitals to choose to report on two of the six available measures, rather than requiring reporting on the Syndromic Surveillance Reporting measure and one other measure selected from the list, as proposed for clinicians for the Promoting Interoperability performance category. **CHA urges the agency to finalize the same flexibility for clinicians under the QPP.**

**Facility-Based Scoring for Quality and Cost Categories**
CMS previously adopted a facility-based measurement scoring option for certain facility-based individual clinicians that begins with the 2019 performance period. **CHA has long advocated for a facility-based quality reporting option for clinicians based in hospitals to align incentives, and appreciates that CMS has proposed policies that would expand the availability of this option to additional facility-based clinicians.**

As previously finalized, a MIPS-eligible clinician furnishing at least 75 percent of his or her professional services in the inpatient hospital or emergency room settings (POS codes 21 or 23) is eligible for facility-based measurement. In this rule, CMS proposes to add services provided in the on-campus hospital outpatient setting (POS code 22) to be considered for determining whether a clinician is eligible for facility-based measurement, as long as the clinician has at least one service billed in POS 21 or 23. **CHA agrees that this approach will help capture clinicians who are primarily inpatient but spend small — yet significant — time providing care in other settings, such as observation units or same-day surgical units based in hospitals. We strongly support this proposal.**

## Medicare Advantage Qualifying Payment Arrangement Incentive Demonstration

CHA appreciates that CMS has made an effort to acknowledge stakeholder requests to recognize the risk associated with Medicare Advantage payment arrangements under the recent Medicare Advantage Qualifying Payment Arrangement Incentive (MAQI) Demonstration. In the proposed rule, CMS proposes regulations to administer the program, including waivers that would exclude MAQI participants from MIPS participation. Due to statutory barriers, the MAQI demonstration as currently designed does not give clinicians access to the 5 percent bonus payment under the Advanced APM track of the QPP. Unfortunately, despite CMS' efforts to recognize Medicare Advantage risk, the MAQI demonstration has missed the mark on several fronts, including the removal of additional clinicians from MIPS without considering demonstration participants as qualifying participants (QP) in Advanced APMs.

CHA members report that, without the added incentive of qualification under the APM track, there is little interest in participation. Further, they note that the current program design is cumbersome, and the timelines set forth for the application process were insufficient to fully evaluate the potential opportunity. **CHA urges CMS to continue to work with stakeholders to address these concerns so that additional Advanced APMs that recognize the risk associated with Medicare Advantage payment arrangements are available for participation.**

## APM Incentive Under the Quality Payment Program

In an alternative to MIPS participation, the QPP provides incentives to clinicians who participate in Advanced APMs. CHA continues to support the development and use of alternative payment and delivery models to reward better, more efficient, coordinated and seamless patient care. We commend the agency for its continued commitment to expanding the availability of such models for hospitals and their physician partners. However, we offer a number of comments that we hope the agency will consider in expanding opportunities for increased participation in advanced APMs.

*Financial Risk Standard Setting for QP Performance Periods 2021-24*
CMS previously finalized the generally applicable revenue-based nominal amount standard initially at 8 percent or greater for qualifying participant (QP) performance period 2020. **We are pleased that CMS has proposed to retain the 8 percent standard for QP performance periods 2021-24, and we support**

**this proposal. However, we continue to urge the agency to recognize the significant up-front investment required of providers that develop and implement APMs. We urge CMS to develop a methodology to quantify and capture up-front investments in APM infrastructure to qualify as financial risk in future models.**

**Other Payer Advanced APM Multi-Year Determinations**
CMS has previously established determinations of Advanced APM status for other payer arrangements. Determinations are valid for one year only, whether based on information submitted through the Eligible Clinician Initiated or the Payer Initiated process. CMS proposes to modify this policy so that it can extend the initial Advanced APM determination for five years or until the end date of the arrangement, whichever occurs earlier, if no payment arrangement changes are made. **CHA agrees that annual submission of other payer payment arrangement information is burdensome, especially since other payers often execute multi-year contracts. We strongly support this proposal.**

**Legal and Regulatory Barriers Must Be Waived Under APMs**
As noted in many of our previous comments on APM development, both federal and state law create serious barriers to clinical integration, which depends on hospitals, physicians, nurses and other caregivers working as a team to ensure that patients get the right care, at the right time, in the right place. Shared savings, gainsharing and other APMs provide important mechanisms for aligning providers' interests to decrease health care costs while improving quality as the health care industry transitions from volume- to value-based payment. **CHA continues to urge the agency to work with Congress to remove legal barriers to permit financial arrangements designed to foster collaboration in health care delivery, and incentivize and reward efficiencies and improvements in care.**

## Request for Information on Promoting Electronic Interoperability

CMS seeks feedback on promoting interoperability and, specifically, how it could use the Medicare and Medicaid CoPs to advance electronic exchange of health information in support of care transitions between hospitals and community providers. As an example, CMS says it might consider revising the hospital CoPs to require that hospitals electronically transfer medically necessary patient information to the other facility when a patient is transferred. Similarly, the agency might require that hospitals electronically send discharge information to a patient's community provider when possible, and to provide discharge instructions electronically to patients or a third-party application, if requested.

CHA appreciates the work undertaken by CMS in recent years to promote a regulatory framework for the Medicare CoPs, which supports our collective goals of high-quality, patient-centered care in a rapidly changing health care delivery system. **However, CHA opposes the creation of additional CoPs to promote interoperability of electronic health information.**

Recent changes in law have demanded more fully integrating health care services, putting the patients' health, safety, well-being and preferences at the forefront. The hospital CoPs in particular are still in need of updating, as many have not kept pace with changes in care delivery or hospital and health system organization and integration. Our regulatory framework must more fully address these changes in both the acute and post-acute care settings. Should CMS proceed down this path, we urge the agency to look more broadly at all the CoPs and prioritize all contemplated revisions. **A piecemeal approach that does not consider implications across the delivery system will likely lead to the need for additional revisions sooner rather than later. The CoPs must be looked at in total, through a shared lens of overarching and agreed-upon principals — not in silos.**

To that end, we request that CMS take this opportunity, under a relatively new administration, to demonstrate leadership in this area and consider a more formal stakeholder engagement process as part of its Patients over Paperwork Initiative. With the initiative's goals as the framework for engagement, working with providers across the continuum of care on a more refined set of guiding principles will assist the agency in prioritizing its work so that providers can anticipate and prepare for what will likely be significant revisions to the CoPs — along with anticipated payment and other regulatory changes that, if not timed sequentially, will pose significant operational and financial challenges. An opportunity to share our perspectives, offer suggestions and participate in an ongoing dialogue about these and other changes with the agency would help foster better understanding and shared expectations, and would allow the field adequate preparation time.

Any revisions, additions or removal of CoPs — regardless of the care setting to which they apply — must address not only the current way care is delivered, but also future care delivery. It is imperative that the development of interpretive guidance be done in consultation with revisions to the CoPs. Surveyor training and oversight of the process must be a top priority for the agency. CHA looks forward to working with CMS on these and other CoP changes.

In response to CMS' more specific request for comments, CHA has previously noted that we support policies and practices for effective and sustainable transitions of care, and commend CMS' previous efforts to update existing CoPs to align with current practices and to clarify expectations of providers. However, we continue to believe appropriate oversight must be balanced with the need for flexibility and innovation, and keeping pace with the current state of health information technology (HIT).

**CHA believes it is premature for CMS to consider requiring interoperability of providers until all have an effective EHR system and can participate effectively in the electronic exchange of information.** Before CMS considers revisions to the CoPs that would require electronic transfer of health information, it must survey the HIT landscape of the entire health system, not just that of acute care hospitals. While hospitals and health systems have made great strides in the adoption of EHRs under the Medicare and Medicaid EHR Incentive programs, and continue the work under the Promoting Interoperability programs, the use of EHRs is not as widespread in other care settings, including many physician offices. Some of the most critical junctures for the exchange of health information are during transitions to care settings such as post-acute and behavioral health providers, who were not incentivized to adopt certified EHR technology under the meaningful use programs. As a result, it is often not possible to effectively exchange electronic information with these providers.

CMS must also understand additional operational challenges that currently present barriers to interoperability. Due to a lack of standardized patient identifier, hospitals continue to have challenges in patient matching. Hospitals experience major challenges in transferring health information for medically indigent patients, who often do not have a primary care provider and may not have a permanent address.

Hospitals also often lack the appropriate contact information when transferring health information to community providers or payers. Section 4003 of the 21st Century Cures Act requires the Health and Human Services Secretary to "directly or through partnership with a private entity, establish a provider digital contact information index for providers and facilities." To date, this digital contact information index has not been established. **CHA urges CMS to work with the Department of Health and Human**

**Services to develop this directory as soon as possible. Until the government helps providers solve the problems of patient matching and fully implements a system of accurate provider and payer contact information, hospitals must choose between complying with federal requirements and opening themselves up to risk of penalty under state and federal law for a privacy breach if protected health information is inadvertently sent to the wrong place or provider. That penalty, in California, comes with a significant fine.**

Any future changes to requirements for electronic transfer of health information must also consider the various legal barriers to increased sharing of health information. In comments on CMS' previously proposed changes to the regulations at 42 CFR §482.13, CHA noted that we believe proposed revisions to the CoPs on patients' right to access their own health information are unnecessary and further confuse the body of law surrounding health information privacy. The Health Insurance Portability and Accountability Act (HIPAA) currently requires hospitals to provide patients access to their medical information with limited exceptions, including certain medical records related to research; prisoners' records where access might jeopardize the health or safety of the patient or other inmates; mental health records where access is reasonably likely to endanger the life or physical safety of the patient; and psychotherapy notes.

Portions of existing regulation (42 CFR Part 2) restrict sharing of substance use disorder (SUD) information, which further complicates the exchange of health information in some cases. Clinicians treating patients for any condition need access to their complete medical histories — including information related to SUD — to ensure their patients' safety and delivery of the highest quality care. Partitioning a patient's record to keep SUD diagnoses and treatments hidden from the clinicians entrusted to care for them, as required by 42 CFR Part 2, is dangerous for the patient, problematic for providers and contributes to the stigmatization of mental and behavioral health conditions. To ensure compliance with 42 CFR Part 2, clinicians must maintain two separate computer systems and two separate medical records. This requirement adds burden and expense, but without benefit. CHA supports efforts to make statutory changes that would amend 42 CFR Part 2 to align with HIPAA for the purposes of treatment, payment and health care operations. Such changes are required before hospitals and other community providers can meaningfully share health information.

These and other issues must be considered both through notice and comment rulemaking, as well as through stakeholder dialogue. CHA stands ready to work with the agency to identify the challenges and opportunities, and solve problems together. Our goals are shared, and we urge CMS to make this a priority going forward. There is tremendous opportunity to advance the regulatory framework in which care is provided, lower costs and decrease burden and — most importantly — make our health care system more patient-friendly.

CHA appreciates the opportunity to share our comments on these important issues. If you have any questions, please do not hesitate to contact me at (202) 488-4688 or akeefe@calhospital.org, or my colleague Megan Howard, senior policy analyst, at (202) 488-3742 or mhoward@calhospital.org.

Sincerely,

/s/
Alyssa Keefe
Vice President, Federal Regulatory Affairs