



**CALIFORNIA
HOSPITAL
ASSOCIATION**

*Providing Leadership in
Health Policy and Advocacy*

August 12, 2019

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

SUBJECT: CMS-6082-NC, Request for Information; Reducing Administrative Burden to put Patients over Paperwork; Federal Register (Vol. 84, No. 112), June 11, 2019

Dear Administrator Verma:

On behalf of our more than 400 hospital and health system members, the California Hospital Association (CHA) appreciates the opportunity to provide the Centers for Medicare & Medicaid Services (CMS) with recommendations on a number of regulatory, subregulatory, policy, and procedural changes that will reduce unnecessary administrative burdens for clinicians, providers, patients, and their families. Despite the administration's efforts to reduce burden in recent years, hospitals and post-acute care providers continue to be challenged by the daunting task of complying with the growing number of overlapping and complex federal regulations. We applaud the agency for continuing to seek innovative ideas for reducing burden while improving care for all of the patients California hospitals serve.

A reduction in administrative burden will enable providers to focus on patients, not paperwork, and reinvest resources in improving care, improving health, and reducing costs. As clinical staff find themselves devoting more time to regulatory compliance, time and resources are increasingly shifted away from patient care, adding costs to the health care system. The timing and pace of regulatory change often result in the duplication of efforts and substantial diversion of clinicians' time away from patient care. As new or updated regulations are issued, providers must quickly mobilize clinical and non-clinical resources to understand the regulations; assess any interaction with state laws and regulations; and then redesign, test, implement, and communicate new processes and workflows throughout the organization. This often involves personnel from across the organization and coordination of infrastructure and financing needs, including technology. As CMS adopts new or revised regulatory policies and procedures, we ask the agency to not underestimate the impact of these changes in terms of direct and indirect cost to the health care system, and to weigh these costs with the return on investment. CMS must allow appropriate time and flexibility for hospitals to implement regulatory change in a manner that puts patients in their community first.

Below, we offer a number of specific recommendations for CMS to consider as it continues its efforts to put patients over paperwork.

Survey, Certification, Quality, and Patient Safety

Improve Processes for Development and Implementation of Revised Conditions of Participation

CHA appreciates the work CMS has undertaken in recent years to promote a less burdensome regulatory framework for the Medicare and Medicaid Conditions of Participation (CoPs). Hospital compliance with the CoPs is important to ensuring patient safety, but inconsistent application of the CoPs has led to significant costs for hospitals. **As CMS and hospitals work toward the collective goal of high-quality, patient-centered care, the CoPs must keep pace and be revised to reflect the innovations of a rapidly changing health care delivery system. As CMS considers revisions to the CoPs, CHA encourages the agency to improve its current processes for development of the CoPs, interpretive guidance, survey training, and provider education in order to reduce burden on hospitals.**

More specifically, CMS should engage stakeholders early on and throughout the CoP development and implementation process, including the development of interpretive guidance. In particular, we appreciate that CMS recently issued two draft policy memorandums for comment on interpretive guidelines for ligature risk and hospital co-location. CMS should continue to utilize 60-day comment periods, as well as advance notice of rulemaking processes, to solicit stakeholder input prior to finalizing revisions to the CoPs or subsequent interpretive guidance. Further, we urge CMS to recognize that immediate compliance with revised CoPs and interpretive guidelines is not always reasonable. CHA commends CMS for including — as part of its draft ligature risk interpretive guidelines — a process by which hospitals can seek sufficient time to comply when established time frames may not be feasible. Moving forward, we encourage CMS to consider using a similar process with other requirements.

Increase Oversight of State Survey Agencies to Eliminate Variation

CHA strongly urges CMS to dedicate additional resources and comprehensive training for all CMS regional offices and state surveyors on an ongoing basis. Current educational programs for surveyors are woefully inadequate and do not keep pace with the rapidly changing nature of care delivery. While we appreciate CMS making surveyor education available to hospitals and the general public, we find the information provided to be inadequate. In the absence of a more robust education curriculum including a formal and transparent process for surveyor evaluation accountability, we will continue to experience inconsistent interpretation of the CoPs from state to state and across California. This variation across state, regional, and federal agency staff adds significant avoidable costs to the health care system, as well as undue burden and uncertainty for providers who make every effort to follow the rules as they understand them. State survey agencies provide a valuable service to CMS, similar to accrediting organizations with deemed status. At a minimum, the expectations, oversight, and accountability should be consistent. We urge CMS to continue to prioritize its oversight responsibilities and improve transparency of such efforts.

Continue to Reduce Burden in Quality Reporting Programs

CHA applauds CMS for its ongoing efforts under its Meaningful Measures initiative to review all hospital quality and pay-for-performance programs and reduce reporting burden on hospitals. We have long advocated for a more meaningful, parsimonious measure set that provides hospitals with clinically important information for performance improvement. CHA encourages the agency to continue to evaluate measures across programs, and specifically urges CMS to consider the following changes.

Permanently Suspend Hospital Quality Star Ratings

Hospitals agree that patients and families should have reliable and valid measures of the care provided by hospitals in their communities; this informs important and personal health care decisions. However,

we continue to encounter challenges in understanding and explaining the CMS hospital five-star methodology to consumers and clinicians. While we appreciate that CMS has proposed a number of changes to its star rating methodology — and recently established a new technical expert panel to provide input on the development and maintenance of the star ratings — we ultimately do not believe an overall star rating system meets hospitals' or patients' needs. Notably, CMS recently announced it would not update the hospital quality star ratings for July 2019, and following previous delays, will continue to post information from December 2017.

Research to date on health literacy and use of such tools tells us we have a long way to go in providing patients with the information they are seeking in a way that is understood. For example, we know that our patients are often seeking quality information on a condition-specific basis — such as mortality for a cardiac condition, or an infection or complication rate for a hip replacement — when “shopping” for their care. Providing these measures individually on Hospital Compare has been the hallmark of our collective transparency efforts and is where, we believe, patients find the most value. When aggregated to an overall hospital rating, the information becomes less useful and, in many instances, inappropriately characterizes the hospital's quality of care. Further, the proliferation of varying star and letter rating systems confuses consumers and diverts hospital attention and resources from meaningful quality improvement efforts. **Unfortunately, we continue to believe that CMS' current methodology to publicly report an overall star rating for each hospital does not meet our shared goals, and we urge CMS to permanently suspend its star rating system.**

[Remove Patient Safety Composite Measure PSI-90](#)

Despite attempts by the developer and CMS to improve the measure, CHA continues to have significant concerns with the underlying lack of reliability and accuracy with individual component PSI measures and their ability to generate actionable data. The burden of reporting this measure significantly outweighs any benefit to continued use in the Hospital-Acquired Conditions Reduction Program. **CHA urges CMS to remove the PSI-90 composite safety measure from the program, under measure removal Factor 8.**

[Reduce Burden in Electronic Clinical Quality Measure Reporting](#)

CHA appreciates that CMS has recognized the burden associated with reporting electronic clinical quality measures (eCQMs) by reducing the size of the available measure set and limiting the reporting periods to a self-selected quarter of data. These flexible reporting requirements have been helpful to hospitals in advancing the reporting of eCQMs while providing flexibility to focus their efforts on measures most important to their quality improvement priorities. However, despite reduced eCQM reporting requirements, hospitals continue to report significant issues with submitting eCQM data in each of the years reporting has been required, including having files rejected and thus requiring burdensome resubmission. CMS has routinely had to delay submission deadlines due to internal, technical limitations of the QualityNet system. **CHA strongly recommends that CMS improve the capacity of the QualityNet portal to receive test and production QRDA-I files and send submission summary and performance reports. If CMS finds that updates to QualityNet are not feasible, we recommend that CMS work with hospitals and other stakeholders to identify alternatives for future reporting, such as a new QualityNet portal, use of an existing eCQM reporting portal, or an alternative to electronic submission of eCQM data files.**

In addition, CMS must ensure that the reporting specifications of eCQMs remain stable throughout the reporting period. Hospitals have expressed frustration at the frequency with which the specifications of

eQMs are changed during the reporting year. These changes make prospective measure performance tracking far more challenging.

Medicaid

Reduce Administrative Burdens on Medicaid Supplemental Payments in Managed Care

CMS' 2017 Medicaid Managed Care final rule imposed new and expansive restrictions on states' ability to utilize targeted payment initiatives in the managed care delivery system. Specifically, the special contract provisions related to payment at § 42 C.F.R. 438.6 have created significant administrative burdens within the Medicaid managed care financing structure. These requirements have created a regulatory environment that is far too complex and overly burdensome on state officials, Medicaid managed care plans, and hospitals. In particular, the timeline for states to receive approval from CMS often requires retroactive implementation dates for Medi-Cal managed care supplemental payment programs, placing significant financial burden on hospitals. These delays are especially troubling for California's safety net providers and the more than 10.5 million patients enrolled in the Medi-Cal managed care delivery system.

For example, included below is an actual timeline of events for the Medi-Cal managed care supplemental payment program for state fiscal year 2017-18 (July 1, 2017-June 30, 2018).

- 1) California submitted the Private Hospital Directed Payment program preprint on June 30, 2017.
- 2) CMS responded within 90 days to the initial request, and exchanged more than four rounds of questions with the state.
- 3) CMS approved the Private Hospital Directed Payment program preprint on March 6, 2018 — almost nine months after submission.
- 4) The state's actuaries finalized the actuarial sound rates in accordance § 42 C.F.R. 438.4 and included the approved Private Hospital Directed Payment program. Rates were submitted to CMS on June 30, 2018.
- 5) To date, CMS has responded to the state with questions regarding the rates, but has yet to formally approve the rates or contracts.
- 6) The state hopes to receive approval before December 31, 2019.

In the real-life scenario detailed above — assuming the state is accurate in its estimate that CMS will approve the rates by December 31, 2019 — CMS' process to review and approve a directed payment program spans more than two-and-a-half years. This impacts not only Medicaid agencies but also hospitals that provided services more than two years before CMS approval was provided. Compare this process to Medi-Cal fee-for-service payments, under which CMS approves most State Plan Amendments within 90 days of submission. As the Medi-Cal program continues to shift into managed care, this timeline places an unsustainable financial burden on hospitals. Given that Medi-Cal reimbursement rates are some of the lowest in the country, averaging around 60% of costs prior to supplemental payments, timely CMS approval is vital to the overall sustainability of California's safety-net hospitals.

CHA urges CMS to withdraw or amend the requirements listed below to improve the administrative process and reduce burden on hospitals.

Eliminate Annual Approval Requirements for Directed Payment 438.6(c) Preprints

States are required to submit "preprints" annually to CMS for their review and approval of the directed payment programs (pursuant to 438.6(c)). This CMS approval process duplicates an existing process

through which managed care rates are submitted annually to CMS and subject to a thorough review by the CMS Office of the Actuary. Seeking a separate approval for preprints is an unnecessary administrative burden for Medicaid agencies and, as illustrated in the example above, delays the entire rate review process. **We urge CMS to withdraw or amend this annual requirement and seek a less burdensome process for evaluation and oversight of state directed payment programs.**

[Eliminate the Network Provider Requirement for Directed Payments 438.6\(c\) Programs](#)

The network provider requirement set forth in 438.6(c) has created a significant barrier for providers to receive 100% of their allowable directed payments. In California, there are more than 24 separate Medi-Cal managed care plans that span 58 counties. Most hospitals today have expansive network agreements with the Medi-Cal managed care plans or delegated plan partners in their region. However, it becomes incredibly burdensome for the hospitals to enter into full network provider agreements with every single Medi-Cal managed care plan statewide. Additionally, the administration of the Private Hospital Directed Payment program has become an increasingly difficult challenge for the state. Hospitals are required to review all encounter-level data by plan/hospital detail, then must validate each individual encounter against their contracts to review for the network provider requirements. Completing this process requires not only months of work, but also demands extensive staffing resources from both hospitals and Medi-Cal managed care plans. As calculated by the state — for the first directed payment cycle of state fiscal year 2017-18 — more than 90% of the encounter utilization data received by the state passed the network provider definition. We understand CMS has had concerns about directing payment to non-network providers, but today's reality is that more than nine of 10 providers in California are in network. **The intense effort by the entire state (hospitals, plans, and state agencies) to screen out the less than one of 10 providers not in network has created a costly administrative burden for everyone. We urge CMS to remove the network provider requirement from the 438.6(c) allowable directed payments and provide states with the administrative flexibility to direct payments to the classes of providers outlined in their rate certifications.**

[Amend the CMCS Informational Bulletin that Caps 438.6\(d\) Pass-Through Payments as of July 5, 2016](#)

CMS released a CMCS Informational Bulletin, subsequent to the final rule, that narrowed states' ability to take advantage of phasing out existing pass-through payment arrangements for hospitals over a 10-year period. Effectively, the CMCS Informational Bulletin clarified that the 10-year phase out would apply to existing and approved hospital pass-through payment programs as of July 5, 2016. In California, this effectively reduced the available pass-through payment program to 50% of the size in effect on July 1, 2017. **We urge CMS to amend the 2016 CMCS Informational Bulletin to allow for more flexibility with the interpretation of this phase-out requirement and to maintain the final rule's initial intent: to allow for a 10-year transition period that will help providers adapt to the new directed payment program requirements.**

[Medicare Payment and Policy Issues](#)

CHA applauds the agency for its commitment to reducing burden for hospitals participating in the Medicare program so that resources can be appropriately focused on patient care. For example, **we are pleased to see that in its calendar year (CY) 2020 outpatient prospective payment system proposed rule, CMS has proposed to adopt a required minimum level of general supervision — rather than direct supervision — for hospital outpatient therapeutic services furnished by all hospitals and critical access hospitals.** CHA has long advocated for this policy, which will be particularly helpful for California's rural communities that face ongoing physician shortages. We urge the agency to continue to address hospital concerns to reduce burden and offer a number of specific recommendations below.

Reduce Burden of Clinical Laboratory Fee Schedule Reporting for Hospital Outreach Laboratories
CHA urges CMS to rescind its requirement that hospital outreach laboratories determine applicable laboratory status based on revenue attributed to Medicare Part B services billed on a 14x Type of Bill (TOB). The significant burden associated with reporting private payer data for non-patients, as described in CMS' February 2019 subregulatory guidance, is counter to the administration's goals to reduce burden and prioritize patients over paperwork. CMS acknowledged that this additional reporting by hospital outreach laboratories is unlikely to impact the payment rates under the clinical laboratory fee schedule (CLFS) in a March 2019 letter to the Senate Finance Committee. In the letter, CMS cited its analysis of the first CLFS data collection period, which found that "additional reporting requirements were not likely to result in a significant change to payment amounts, irrespective of how many additional laboratories reported." In light of this analysis, we urge the agency to allow hospital laboratories to focus their resources on patient care by removing its separate requirement that hospital outreach laboratories determine their applicable laboratory status using only Medicare revenues billed on a 14x TOB.

Based on an analysis of 2017 Medicare fee-for-service claims data, CHA estimates approximately 90 hospital laboratories in California would exceed the low-volume threshold based on their 14x TOB revenue and thus be determined applicable laboratories. CMS has vastly underestimated the burden associated with identifying non-patient laboratory services for the purposes of reporting separately payable private payer rates.

In the absence of rulemaking to rescind this requirement, the agency should take steps to simplify reporting for hospital outreach laboratories by requiring reporting only of private payer data billed using a 14x TOB. This is a simple change that can be addressed in subregulatory guidance and aligns with the agency's stated position that reporting is unlikely to impact payment rates. CMS' current guidance states, "It is the hospital's responsibility to identify, collect and report the separately payable private payor rates (and the volume of tests paid at those rates) that are associated with only the outreach laboratory portion of the hospital's laboratory business." This requirement has already forced hospitals to develop highly burdensome processes to determine and report these private payer rates, directing significant resources away from patients and to paperwork. In many cases, private payers do not require that hospitals use the 14x TOB to bill for non-patient services, and may instead require other forms of billing in their private contracts. Absent a federal definition of "hospital outreach laboratory services," hospitals use varying methods to track and bill payment for services provided to non-patients, and many have found it impossible to identify and collect separately payable rates for these services.

Eliminate Appropriate Use Criteria Facility Reporting Requirements

CMS has established a number of regulations to implement appropriate use criteria (AUC) for advanced diagnostic imaging services. 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 appreciate that CMS has taken a thoughtful approach to program implementation with a delayed start date of January 1, 2020. However, we continue to have concerns about the burden and operational challenges this program will pose for hospitals. We urge the agency to withdraw its policy that requires AUC consultation information on the facility claim.**

In the CY 2019 physician fee schedule final rule, CMS revised 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; therefore, we believe CMS has significant flexibility to revisit its assumptions in light of the burdens associated with reporting.**

More importantly, as identified by National Uniform Billing Committee, 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 are tied to the actual procedures performed. In addition, multiple procedures could be performed during one outpatient visit (e.g., surgery and advanced imaging), requiring multiple physicians to be involved in care provision. 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. As a result, 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 will 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.**

[Reduce Overreliance on Billing Modifiers](#)

Over the past several years, CMS has required the use of an increasing number of HCPCS modifiers. CHA is concerned that an overreliance on billing modifiers increases burden in both the preparation and submission of bills. In addition to the modifiers and G-codes that will be required to report AUC consultation, CMS has recently implemented the following modifiers:

- **FX modifier:** X-ray taken using films
- **FY modifier:** X-ray taken using computed radiography technology/cassette-based imaging
- **PO modifier:** Services, procedures and/or surgeries furnished at off-campus provider-based outpatient departments, reported with every code for outpatient hospital services furnished in an off-campus provider-based outpatient department of a hospital
- **PN modifier:** Non-expected service provided at an off-campus, outpatient, provider-based department of a hospital
- **JG modifier:** Drug or biological acquired with 340B Drug Pricing Program discount
- **TB modifier:** Drug or biological acquired with 340B Drug Pricing Program discount, reported for informational purposes

In addition, CHA believes CMS could reduce burden on providers by removing the requirement that the "JW" modifier be reported on certain Part B drug claims for discarded drugs/biologicals in single-dose or single-use packaging. Compliance with this requirement requires complex coordination and specialized information technology solutions. This modifier is particularly burdensome for hospitals participating in the 340B program, which must also report the "JG" and "TB" modifiers on the claim; if the drug is provided in an off-site provider-based outpatient department, the "PO" modifier must also be included. This increasing level of complexity results in more coders and billers being hired than nurses and

doctors. Further, CMS requires both the amount of medication administered and the amount of medication discarded to be recorded on the patient's bill as well as in the patient's chart. The possibility of human error is increased in entering and reviewing the record during the course of treatment, potentially introducing patient safety concerns.

These issues are further exacerbated when Medicare adopts very specific modifiers — for only the Medicare population — that conflict with other commercial payers. This conflict often prevents claims from being accepted when crossover billing is required (e.g., with respect to Medicaid or Medi-gap). CHA urges CMS to undertake a comprehensive review of all modifiers and to prioritize those that are absolutely necessary for payment.

[Eliminate Exact Address Match Requirements for Hospital Outpatient Providers with Multiple Locations](#)

In an effort to ensure correct payment for services furnished in off-campus provider-based departments of hospitals, CMS plans to enact billing changes for outpatient prospective payment system providers that have multiple locations. Specifically, the agency has indicated it will put in a system edit to check whether the address on a provider's claim **exactly matches the address** the provider entered into the Medicare Provider, Enrollment, Chain and Ownership System (PECOS). When CMS fully activates the edit — which has been delayed until at least October 2019 — the Medicare administrative contractors (MACs) will "Return-to-Provider" any claims where the addresses do not exactly match. For example, if a provider's enrollment information includes a service location with the word "Road" but the provider entered "Rd" as part of their address on the claim, the claim would be returned to the provider. Hospitals would then be required to resubmit these claims to their MAC. **CHA believes that such an "exact match" requirement is unnecessarily burdensome and will result in a time-consuming and disruptive process of claims resubmission due to the use of common abbreviations and minor typographical errors. The United States Postal Service can deliver mail to a "road" or to "Rd" for millions of Americans six days a week. Such an edit to its systems would disrupt the mail delivery service for the entire nation. The same is true for Medicare and the millions of claims processed each day.**

Until now, MACs have processed payments using common-sense judgements to determine address matches. CHA urges CMS to rescind its overly prescriptive system edit that will require the address on a provider's claim to exactly match the provider's address in the PECOS.

[Improve the Targeted Probe and Education Process](#)

CHA appreciates that CMS has implemented a targeted probe and educate (TPE) process to improve the MAC audit processes; this has been a hallmark of the agency's burden reduction initiative. We believe the time is right for CMS to evaluate and take steps to improve the TPE process, further reducing the burden on hospitals. For example, while the TPE requires MACs to focus only on providers and suppliers with the highest claim denial rates or billing practices that vary significantly from their peers, CMS has not outlined a specific error rate that would automatically trigger advancement through the TPE process on any particular review. Rather, the agency error rate that qualifies a provider or supplier for TPE varies based on the provider and the service/item under review; it may further vary depending on the MAC. This has resulted in discrepancies in application of probe and educate standards between MACs and confusion in health systems working to drive performance improvement across all hospitals. This process rewards compliant providers with less oversight, but subjects those selected for a probe and educate review to significant burden because, if they have not sufficiently improved after three rounds

of review, they could face actions such as referral to a recovery auditor, extrapolation, or 100% pre-pay review.

In addition, a number of reviews underway are direct results of a hospital providing a service following a physician referral and subsequent order. For example, a hospital provides a patient with an X-ray. The medical necessity review is performed on the hospital claim, and it is found that the medical record documentation does not support medical necessity for the service provided — in this case the X-ray. Much of that information is contained in the physician medical record that may or may not be integrated with the hospital record. As such, providers are subject to continual review on an issue over which they have little control. A Part B review of the physician claims aligned with the hospital review would promote alignment and more quickly drive down error rates. **CHA urges CMS to consider piloting crossover reviews of services provided and to incorporate those findings into the TPE processes. In certain instances, crossover claim reviews are necessary to ensure alignment. We urge the agency to explore those opportunities.**

Finally, CHA is concerned that CMS continues to have a significant backlog of providers currently advanced by the MACs for referral to recovery audit contractors (RACs). The lack of transparency in this referral process and communication with providers regarding their current status is unsettling. Furthermore, CMS has not been transparent about how a provider would be removed from endless RAC review once they are referred for a RAC audit. **CHA urges CMS to improve communications with providers so that steps can be taken to address concerns and to make transparent the process for removal from RAC review once referred.**

[Eliminate the Observation Hours Carve-out Policy](#)

CHA urges CMS to eliminate the requirement that hospitals “carve out” from their count of observation hours the time involved in furnishing other diagnostic or therapeutic services that also require active monitoring. This requirement is burdensome for hospitals, as it requires manual estimation and recording of the time required to complete each separate service. It is also unnecessary given that payment for observation services is now packaged and, in most cases, diagnostic or therapeutic services furnished in conjunction with observation are no longer separately paid. Further, in CMS’ final policy for implementing the Notice of Observation Treatment and Implication for Care Eligibility Act, hospitals are instructed to disregard the notion of “billable hours” for the purposes of triggering the timeline for issuing the Medicare Outpatient Observation Notice. Instead, they are directed to count the time directly as clock hours from the initiation of observation services.

[Eliminate Second Important Message from Medicare](#)

CHA urges CMS to eliminate the burdensome and redundant requirement that hospitals provide the “Second Important Message” from Medicare explaining a beneficiary’s appeal rights if the initial written explanation was provided and signed more than two days prior to discharge. We believe that providing this information twice in one stay is confusing and overwhelms patients with unnecessary paperwork.

[Allow Non-Physician Workforce to Practice to Scope of State Licensure](#)

As the training and expertise of the non-physician workforce has advanced, hospitals find that Medicare regulations have not kept up. These outdated policies often prevent registered nurses, pharmacists, physical therapists, and other licensed staff from working at the top of their licenses, as permitted by state law. For example, when working under Nursing Standardized Procedures, the State of California allows registered nurses to perform certain activities that otherwise would be considered the practice of

medicine, such as ordering tests for commercially insured patients so that the results will be available when the physician sees the patient. However, current CMS regulations at § 42 C.F.R. 410.32(a) prevent them from doing the same for Medicare beneficiaries. CMS should update its application to nonphysician practitioners – currently limited to clinical nurse specialists, clinical psychologists, clinical social workers, nurse-midwives, nurse practitioners, and physician assistants – to include any nonphysician practitioner or other staff working collaboratively under the physician’s supervision and within the scope of their license under state law. Similarly, CMS should permit non-physician practitioners — as licensed by the state — to approve therapy and home health plans of care and certify need for durable medical equipment, and allow all for electronic sign-offs. Taking these steps would free physicians to concentrate on the most complex and challenging aspects of patient care.

[Improve Timely Access to Durable Medical Equipment for Medicare Beneficiaries](#)

California hospitals and post-acute care providers have previously reported significant difficulties in obtaining timely delivery of medically necessary durable medical equipment (DME) for Medicare beneficiaries upon hospital discharge. Since the implementation of the Competitive Bidding Program (CBP) for durable medical equipment, prosthetics, orthotics and supplies (DMEPOS), this issue has become increasingly acute. Despite the recent suspension of the CBP, hospitals continue to experience challenges and have had to dedicate significant resources to develop burdensome work-arounds to ensure Medicare beneficiaries are sent home with the necessary DME that these suppliers should be required to provide. Case managers in particular are often diverted from other duties, like patient and caregiver education and training or care coordination.

As documented in CHA’s [September 2018 issue brief](#), the administrative burden and financial resources that hospitals and post-acute care providers must expend to register their complaints related to CBP DME suppliers — and, concurrently, to implement work-around strategies to obtain the medically necessary DME for patients — have grown exponentially in recent years. CMS should take a number of administrative steps to reduce the burden of obtaining DME on beneficiaries and providers, regardless of the status of the CBP program. Specifically, CHA recommends that CMS:

- Improve the Medicare Supplier Directory to include real-time equipment availability status, estimated delivery times, and specific service delivery areas by DME supplier. The lack of a steady and reliable resource for routinely ordered DME creates a significant and costly administrative burden for providers, as well as the beneficiaries who rely on hospital case managers to support safe, timely hospital discharge.
- Revise the DMEPOS quality standards to further clarify the term “timely as agreed upon by the beneficiary and/or caregiver, supplier, and prescribing physician.” Revisions to the timely delivery quality standards should, in the case of a patient discharge from a hospital or other provider, require delivery of DME items that the ordering physician determines are essential for patient safety and continued recovery prior to the patient’s discharge date, as specified by the providers and ordering physician.
- Remove the reference to a five-day window for order response, specifically for DME items that are needed for safe discharge to home or community.
- Increase oversight of DME suppliers and establish transparent performance metrics for assessing whether suppliers meet each quality standard. Such metrics could be reported and incorporated into future CBP contracts.

Reduce Burden on Post-Acute Care Providers

As detailed in CHA's comments on the federal fiscal year (FFY) 2020 post-acute care prospective payment system (PPS) proposed rules ([IRF PPS](#), [LTCH PPS](#), [SNF PPS](#)), CHA remains concerned about the burdens that post-acute care providers face in implementation of the Affordable Care Act and the IMPACT Act, including development and implementation of quality measure domains using standardized patient assessment data elements (SPADEs). Unfortunately, the final FFY 2020 post-acute care rules largely adopt CMS' proposed policies to significantly increase the data collection and reporting requirements across post-acute care settings. The actual time and cost impact of these new requirements will be considerably higher than CMS estimates.

CHA and its member hospitals, which represent the full range of acute and post-acute care service providers, recognize the importance and value of post-acute care payment reform, including SPADEs. Furthermore, CHA supports CMS' work to more closely align the post-acute care payment systems with patient characteristics and resource needs. While CMS has moved ahead, we believe the following recommendations should continue to be considered as viable options for staging implementation and reducing provider costs and burden moving forward. CHA urges CMS to consider the following recommendations:

- Reduce the speed and scope of SPADE implementation. A more gradual, phased-in approach would enable electronic medical record providers, software vendors, and facilities to develop and test data collection procedures that will stand the test of time and not cause unnecessary expense.
- Create and make transparent a data use strategy and analysis plan for the SPADE items so post-acute care providers better understand how the agency will further assess SPADEs' adequacy and usability in the development of a unified PPS and future quality measures.
- Develop a framework in the current post-acute care data collection systems (e.g., IRF-PAI, MDS, LCDS, etc.) for prioritizing implementation of the critical SPADEs. The agency should strongly consider a period of voluntary reporting for a number of SPADEs to better understand their value in future data use strategies.
- Detail and adopt a staged implementation plan to allow post-acute care providers additional time to manage the operational and workflow changes needed to ensure reliable and valid data collection across all patients. Additional evaluation of SPADEs and their intended uses is needed prior to nationwide implementation and adoption.

Reduce Burdensome Legal and Regulatory Barriers under Alternative Payment Models

California hospitals are committed to participating in alternative payment models (APMs) to reduce health care costs while improving quality, accountability, and efficiency. However, a number of federal regulatory requirements and legal barriers make participation in these models overly burdensome and have slowed the shift toward the use of risk-based payment models. In addition, California hospitals face unique challenges under stringent state fraud and abuse laws, as well as one of the strongest bans on physician employment in the United States, making flexibility at the federal level even more critical. **CHA urges CMS to take steps both administratively and in coordination with Congress to address a number of [recommendations previously provided](#) to reduce burden on hospitals while shifting to new models of care that will improve health care costs and quality for patients. These recommendations include:**

- Reform the Stark Law, anti-kickback statute, and civil monetary penalties to allow appropriate alignment of the financial interests of members of the health care team participating in APMs, including hospitals and clinicians.

- Streamline and simplify program waivers across all APMs wherein hospitals assume financial risk.
- Waive current hospital discharge planning requirements that prohibit, or otherwise limit, information hospitals may provide on post-hospital services in models that hold participating hospitals financially accountable for quality and costs for the entire episode of care so that the hospital has the flexibility to direct patients to the most clinically appropriate next setting of care.
- Waive the inpatient rehabilitation facility “60% rule” under APMs, which are often intended to decrease the volume of patients referred to these facilities.
- Waive the three-hour requirement for therapy under models that include a voluntary per-diem type payment method.
- Waive the LTCH 25-day length of stay requirement under APMs.
- Waive the prohibition on home health agencies performing free pre-operative home safety assessments for patients scheduled to undergo surgery, and provide payment for pre-admission visits to result in more informed post-acute care planning.
- Waive the requirement that a beneficiary be “home-bound” in order to receive home health services under APMs.
- Waive the skilled-nursing facility three-day rule under APMs, without the limitation that such a waiver be allowed only in certain performance years, or to only those facilities with at least a three-star rating in the Five-Star Quality Rating System on the Nursing Home Compare website.

[Continue to Improve S-10 Data Integrity While Reducing Burden on Providers](#)

CMS recently completed reviews of Worksheet S-10 for FFY 2015 and is currently undertaking additional audits of a subset of hospitals for FFY 2017. **CHA applauds the agency’s efforts to review these data to ensure they are reliable and accurate for purposes of payment. Further, the cost report data are provided in an easily accessible and widely utilized database that is used by policy makers as well as health policy researchers and the media. Continued review of this data is imperative, and we urge the agency to adopt audits for all hospitals eligible for Medicare disproportionate share hospital payments. To streamline this process, making it easy for MACs and providers to comply with audits on a compressed timeline, we urge the agency to adopt the following recommendations:**

- **Build infrastructure and look to the field for technology solutions.** We learned very quickly that the data needed to accurately report Worksheet S-10 are far too robust to produce meaningful information, and Microsoft skills are not adequate to manage the amount of data necessary to report uncompensated care. CMS, MACs, and providers must work together to identify meaningful technology solutions that will allow all parties to work effectively with these large datasets so we can work efficiently and consistently. This will significantly decrease audit costs.
- **Educate auditors.** Many auditors have a finance background, but not a patient financial services background. General education on how hospitals implement and record transactions based on their charity care and financial assistance policies would promote shared understanding and expectations. In addition, various state and federal requirements influence how a facility may write and implement its policies, particularly with respect to section 501R of the tax code, which imposes requirements on financial assistance policies for not-for-profit hospitals. CMS acknowledges and allows for variation of these policies as needed. However, there seems to be a “one size fits all” approach to reviewing these policies’ language — an approach that may not be appropriate. Additional education, training, and resources will limit auditor variation and reduce cost and time needed to complete the audits.

- **Engage and educate providers.** Much has been learned through these reviews, and we anticipate that CMS and the MACs may identify best practices for reporting. CHA encourages the investment of significant staff resources to develop educational forums and opportunities for ongoing dialogue between CMS, MACs, and hospitals **prior** to the release of substantive revisions to or guidance on cost report instructions. CHA believes that CMS should release draft guidance or instructions prior to their adoption to help bring about shared understanding of expectations and ensure more accurate reporting in the future.

Privacy, Security, and Access to Patient Health Information

As CMS pursues policies to improve the interoperability of health information and give patients more convenient access to their health care records, we urge the agency to view privacy regulations in their totality and align requirements, rather than add onto an already overly complex regulatory framework. For example, federal regulations established under the Health Insurance Portability and Accountability Act (HIPAA) apply to health systems, hospitals, and post-acute care providers and are designed to ensure the security and privacy of patient health information while establishing patients' rights to access their health information. However — as detailed in [previously submitted comments](#) — we are concerned that recently proposed regulations on information blocking released by the Office of the National Coordinator for Health Information Technology (ONC) unnecessarily complicate hospital compliance with privacy regulations, while introducing new security concerns and adding administrative burden. ONC should work with CMS, the Department of Health and Human Services Office for Civil Rights (OCR), and Congress to align requirements for information blocking within the HIPAA framework.

Similarly, current provisions of § 42 C.F.R. Part 2 relating to individuals receiving services from substance use disorder (SUD) programs have created a huge barrier to providing high-quality, coordinated care. These regulations restrict sharing of SUD information, which often denies clinicians treating patients with a SUD access to their complete medical histories. The only way to properly treat the whole person is to have all the information about the whole person. For example, knowledge of a patient's prior SUD history is essential for proper pain management after surgery. To ensure compliance with § 42 C.F.R. Part 2, clinicians must maintain two separate computer systems and two separate medical records, adding significant burden and expense. CHA supports efforts to make statutory changes that would amend § 42 C.F.R. Part 2 to align with HIPAA for the purposes of treatment, payment, and health care operations.

CHA appreciates the opportunity to respond to this request for information. If you have any questions, please do not hesitate to contact me at akeefe@calhospital.org or (202) 488-4688, or Megan Howard, senior policy analyst, at mhoward@calhospital.org or (202) 488-3742.

Sincerely,

/s/

Alyssa Keefe
Vice President, Federal Regulatory Affairs