



September 9, 2019

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 314-G
Washington, D.C. 20201

SUBJECT: CMS-1711-P, Medicare and Medicaid Programs; CY 2020 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model; Home Health Quality Reporting Requirements; and Home Infusion Therapy Requirements; Proposed Rule, Federal Register (Vol. 84, No.138), July 18, 2019.

Dear Administrator Verma:

On behalf of our more than 400 member hospitals and health systems, including many home health agencies (HHAs) operated by hospitals and health systems, the California Hospital Association (CHA) is pleased to submit comments on the Centers for Medicare & Medicaid Services (CMS) home health prospective payment system (PPS) proposed rule for calendar year (CY) 2020.

CHA supports and appreciates CMS' proposals to:

- **Modify regulations to allow therapist assistants to provide maintenance therapy under the home health (HH) benefit.**
- **Change requirements for the HH plan of care.**
- **Change the specification for the HH Quality Reporting Program (QRP) measure "Discharge to Community – PAC."**
- **Remove selected pain measures from the HH QRP.**

CHA urges CMS to:

- **Eliminate the prospective payment adjustments associated with the estimated impact of behavioral assumptions and consider, after transparent analysis, a retrospective adjustment informed by such analysis and impact of these payment policies on patient access to home health services.**
- **Analyze and make available a financial impact analysis (inclusive of assessment of timely payment) of the Patient Driven Groupings Model (PDGM) on existing HHAs prior to final elimination of the split percentage payments to HHAs.**
- **Allow HHA nurses to conduct the required discussion of options for obtaining infusion, under supervision of the physician responsible for the plan of care.**

Specific to CMS' proposals for multiple additions to data collection and patient assessment, including the implementation of standardized patient assessment data elements (SPADEs), CHA urges CMS to:

1. **Modify the speed and scope of SPADE implementation.** HHAs and other post-acute care (PAC) providers would benefit from a more gradual implementation, including a period of voluntary

data collection and non-enforcement of data collection thresholds, in order to assess and test re-designed workflow processes that could more efficiently and effectively meet the goals of an accurate assessment and inter-setting communication.

2. **Create and make transparent a data use strategy and analysis plan** for the SPADE items so post-acute care providers, including HHAs, better understand how the agency will further assess SPADEs' adequacy and usability in the development of a unified PPS and future quality measures, including the development and implementation of a process to assess the value of specific indicators for all patient types.

CHA strongly supports the goals of the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014 and appreciates CMS' ongoing efforts to improve payment accuracy, including aligning reimbursement with patient characteristics and standardizing patient assessment items across care settings. However, the scope of these changes and their timing remain problematic.

HHAs and other PAC providers are undergoing unprecedented change, including case-mix changes and the significant addition of SPADEs, which will require additional staff training and development, as well as implementation of new operational procedures. Rethinking this implementation — and staging it appropriately — will benefit both providers and CMS in the long term. Our detailed comments follow.

CMS' APPROACH TO PPS CHANGES FOR POST-ACUTE CARE PROVIDERS

CHA shares CMS' goals of ensuring that patients receive post-acute medical and rehabilitative care in the setting most appropriate for their needs, and that patient assessment practices support effective care treatment plans and transitions. We also recognize CMS' continued work toward its long-term goal of a unified post-acute care payment system.

In the past 18 months alone, significant changes have been proposed and implemented in each post-acute care payment system. **We urge the agency to develop additional lines of communication with stakeholders, such as a:**

- **Multi-disciplinary stakeholder workgroup**, representing all post-acute settings, to advise CMS on the strategic and operational implications that should be considered as these concurrent changes go forward. We recommend specific emphasis on implementation of the SPADEs across settings. Convening the full continuum of providers offers an opportunity for shared learning and understanding, and allows for discussion of a common analysis framework — while still allowing CMS to engage in a dialogue about the impact on patient care. Such a group (or groups) would help the agency in meeting its long-term goals of a unified post-acute care PPS, as stakeholder engagement conducted only in payment silos is counter-intuitive. While we appreciate the stakeholder engagement to date, formalization of a workgroup representing post-acute care settings would promote shared dialogue between stakeholders, rather than only between individual stakeholders and CMS.
- **Data analytics advisory group** to assist CMS and its contractors in establishing a framework for SPADE analysis and ongoing assessment.

CHANGES TO THE HH PPS CASE-MIX SYSTEM FOR CY 2020

In the CY 2019 HH PPS final rule, CMS finalized the implementation of a new patient case-mix methodology. Effective January 2020, the Patient Driven Grouping Model (PDGM) will be used to classify

each patient into a home health resource group payment category. In the current proposed rule, CMS updates payment rates with more recent payment year data in a budget-neutral manner.

CHA supports the overall goals of the revised case-mix methodology, including the transition away from rates largely driven by therapy utilization to those based on patient characteristics. However, we are acutely aware that the implementation of PDGM represents a major change for HHAs, which will require significant staff training and other operational considerations.

Additionally, the effect of PDGM implementation on HH care and access is unclear. The current payment system provides a strong incentive to HHAs to provide therapy services, and possibly to avoid patients with more complex nursing needs. CHA supports the “re-balancing” that PDGM represents and is optimistic that, over time, it will facilitate transition from hospital to HH for medically complex patients, and limit the over-use or over-emphasis of therapy services. However, some CHA members have expressed concerns that some HHAs will respond to the implementation of PDGM by limiting the provision of therapy services or react to the uncertainty of PDGM by limiting patient admissions all together.

As implementation continues, CHA strongly urges CMS to:

- **Provide comprehensive, accessible, and timely provider guidance and training to support a shared understanding of scoring criteria and assessment procedures.**
- **Closely monitor patient assessment data on an ongoing basis, and reassess and modify case mix groupings as needed.**
- **Actively monitor HH access, as well as provision of therapy services, in order to identify and address any negative impact on patient access to medically necessary care.**

BEHAVIORAL OFFSETS

In the 2019 final rule, CMS finalized the implementation of a change in the unit of payment from a 60-day episode of care to a 30-day period of care, as mandated by the Balance Budget Act (BBA) of 2018. The BBA also mandated that the transition be implemented in a budget-neutral manner. Additionally, the BBA requires the Secretary to make certain assumptions about changes in patterns of service delivery that might occur due to the shorter unit of service, as well as changes in case-mix adjustment factors, and incorporate them in the calculation of the standard prospective payment amount. Beginning in 2020 and ending in 2026, the Secretary must determine for each year the difference between the estimated impact of the behavior changes it assumed, and make offsetting adjustments as indicated.

CMS identifies three behavioral assumptions, including: 1) among available diagnoses, the one associated with the greatest reimbursement will be designated as primary; 2) comorbidity adjustments will change to increase payment; and 3) one-third of Low Utilization Payment Adjustment (LUPA) visits that are one to two visits away from threshold will get extra visits in order to achieve a full 30-day payment. CMS estimates the cumulative effect of these adjustments to be negative 8.01%.

CHA recognizes the statutory requirement to develop assumptions about how provider behavior may change under the implementation of the PDGM, and to make appropriate adjustments to the standardized prospective payment amount. However, as stated in comments submitted in response to the 2019 proposed rule, we continue to believe that CMS has not provided sufficient evidence to

support the specific assumptions and their associated financial impact. **Consequently, CHA urges CMS to modify the proposed implementation of payment adjustments associated with the estimated impact of behavioral assumptions and consider a retrospective payment adjustment when more data are available to inform such an analysis.**

As compared with free-standing HHAs, agencies operated by hospitals and health systems that care for a wider range of medically complex patients often operate at minimal, or even negative, Medicare margins. An application of a “one-size fits all” reduction to the standard payment rate, as proposed, unfairly penalizes those agencies. Moreover, the many changes to the PPS in recent years — including rebasing, legislative cuts, and limitations to home health payments — have disproportionately affected HHAs that care for the most medically complex and frail patients.

We urge CMS to provide additional information and data to support its current assumptions about the impact of provider behavior on payment, including an analysis of the projected impact on different types of HHAs, including hospital-based HHAs.

While we understand that CMS will continue to monitor these changes and make offsetting adjustments as indicated, we are concerned that the prospective application of a behavioral adjustment of this size will negatively impact many HHAs and may have unintended consequences for beneficiary access. **We strongly encourage CMS to consider a phase-in of the behavioral adjustments over several years.** A more gradual process, including ongoing analysis of payments relative to resource use and cost, will ultimately result in greater payment accuracy and will limit the possibility of unnecessary interruption in access to HH services.

SPLIT PERCENTAGE PAYMENTS

In 2019 rule-making, CMS initially proposed the elimination of split percentage billing for all HHAs. CHA appreciates the modification CMS made in the 2019 final rule to limit the elimination to newly certified agencies. We believe that allowing existing HHAs to adjust to the implementation of PDGM, including the transition to a 30- day payment period, without the simultaneous change in the split-percentage payment process, will allow greater opportunity to assess associated changes in cash flow and operational procedures, and to prepare for CY 2021. **While CHA is supportive of CMS’ current proposal to standardize this process across all HHAs, we urge CMS to review the impact of PDPM on existing HHAs and their cash flow prior to final implementation.**

PROVISION OF MAINTENANCE THERAPY BY THERAPY ASSISTANTS

CMS proposes to allow therapist assistants to perform maintenance therapy for home-based patients under a therapy program established by a qualified therapist, in accordance with individual state practice requirements. A qualified therapist would still be responsible for the initial assessment, plan of care, maintenance program development and modifications, and reassessment every 30 days, as well as supervision of services provided by the therapist assistant.

CHA appreciates CMS’ recognition that home-based patients require and benefit from both restorative and maintenance services. CHA supports CMS’ efforts to standardize definitions and policies across care settings, and to provide greater flexibility in resource utilization. **CHA also supports the proposal to modify regulations to allow therapist assistants, rather than therapists only, to provide maintenance therapy under the home health benefit.**

In response to questions that CMS posed in the proposed rule, CHA member HHAs do not feel that this provision would require the supervising therapist to provide more frequent reassessments, as this provision would align the requirement with the existing standard in other settings and for restorative therapy in HH. Rather, CHA believes that utilization of therapist assistants within their scope of practice to provide maintenance as well as restorative therapy will support continued access to therapy services and improve overall quality of care.

Adequate access to both restorative and maintenance therapy services is essential to sustained improvement of an individual's functional status, a key factor in controlling readmissions and unnecessary health care utilization. As stated previously, the current move away from therapy utilization as a key driver of rates may lead some HHAs to reduce overall therapy utilization — in particular, services provided by higher cost personnel. This proposal represents a necessary level of flexibility that will support HHAs in their efforts to ensure beneficiary access to all medically necessary services and effective (and cost-effective) use of available resources.

HOME HEALTH PLAN OF CARE

Current regulations require that the plan of care must include several specific items, including a description of the patient's risk for emergency department visits and hospital admission, all necessary interventions to address underlying risk factors, and information related to advanced directives, as provided in the HH Conditions of Participation. CMS is concerned that the current requirements may be too prescriptive and interfere with timely payments for otherwise eligible episodes of care, and proposes that violations for missing items be addressed through the survey process rather than claim denial.

CMS proposes to change regulation text to state that for HHA services to be covered, the individualized plan of care must specify the services necessary to meet the patient specific needs identified in the comprehensive assessment, and must include identification of the responsible discipline(s) providing services and the frequency and duration of all visits, as well as the items specified to establish the need for services. All care provided must be in accordance with the plan of care.

CHA supports CMS' proposal to change HH Plan of Care requirements. CHA agrees that this change will reduce administrative burden and may reduce payment delays for eligible periods of care, while preserving overall standards for HH operation and patient care. In addition, we urge the agency to issue specific educational guidance to assist in facilitating appropriate documentation, so that post-payment reviews of the plan of care are consistent with the education provided in how best to document the plan of care requirements under this change.

INFUSION THERAPY

In the 2019 HH PPS rule, CMS finalized a payment system for the establishment of a new home infusion therapy benefit, as required by the 21st Century Cures Act, to start in CY 2021. During CYs 2019 and 2020, a temporary transitional payment system is in place.

In addition to updates for the temporary transitional payment, CMS now makes proposals for the permanent (CY 2021) system, in order to provide home infusion therapy suppliers adequate time to

prepare. Specifically, CMS proposes to use the three payment categories that reflect similar payment types, each corresponding to a single payment amount in accordance with the Physician Fee Schedule.

The Cures Act requires the physician who establishes the care plan to provide notification to the patient of options available for furnishing infusion therapy under the Medicare Part B benefit; CMS requests comments regarding the form and manner of this communication.

CHA appreciates the opportunity to comment on this provision. Many CHA member HHAs provide home infusion therapy services in partnership with home infusion pharmacies. In such instances, home health nurses will be the most effective link to patients regarding their option for infusion therapy. **CHA recommends that CMS allow HHA nurses to conduct the required discussion of options for obtaining infusion, under the supervision of the physician responsible for the plan of care, when home infusion therapy services are provided by a qualified HHA or the home infusions are part of a plan of care that also includes home health services.** Such a process would allow for consideration of options in the context of the patient's overall medical and functional status, and in accordance with their stated goals and preferences for care.

HOME HEALTH QUALITY REPORTING PROGRAM

CHA supports the currently proposed changes to the HH QRP and recognizes that these changes are part of a multi-year process to reform patient assessment and quality reporting across multiple levels of care.

Addition of Transfer of Health Information Measure

CMS now proposes to add two new process measures for the HH QRP. Specifically, for patients discharged or transferred after January 1, 2021, HHAs would report data for the quality measure domain entitled "Transfer of Health Information." The first proposed measure, "Transfer of Health Information to the Provider – PAC," would assess whether a current reconciled medication list is given to the subsequent provider when a patient is discharged or transferred from his or her current post-acute care setting. The second proposed measure, "Transfer of Health Information to the Patient – PAC," would assess whether a current reconciled medication list was provided to the patient, family, or caregiver when a patient was discharged. If finalized, HHAs would be required to submit data on these measures beginning in January 2021.

CHA supports the addition of measures to address the transfer of "health information" domain, and we recognize that the accurate communication of a current reconciled medication list to PAC providers, patients, and caregivers is critical to safe and effective care transitions. While we remain concerned that these measures present many implementation challenges, **CHA supports the addition of these measures to the HH QRP. We urge CMS to pursue the rigorous National Quality Forum (NQF) endorsement process for both measures and to continue to refine and improve feasibility.**

Discharge to Community Measure Specification

CHA strongly supports CMS' proposal to update the specifications for the Discharge to Community PAC HH QRP measure to exclude baseline nursing facility residents. CMS has found that rates of discharge to community from an HHA were significantly lower for baseline nursing facility residents compared with non-nursing facility residents. Baseline nursing facility residents are defined as HH patients who had a long-term nursing facility stay in the 180 days preceding their hospitalization and HH

episode, with no intervening community discharge between the nursing facility stay and qualifying hospitalization. CHA appreciates CMS' responsiveness to stakeholder comments on this issue.

Pain Measures

CMS proposes to remove the Improvement in Pain Interfering with Activity measure from the HH QRP, and the question "In the last 2 months of care, did you and a home health provider from this agency talk about pain?" from the HH Consumer Assessment of Health Providers and Systems (HCAHPS) survey. CMS notes it is making this change, which is being made in all care settings, in order to avoid any unintended consequences for the prescription of opioids for pain management. If finalized, this data would no longer be publicly reported on HH Compare after April 2020, and HHAs would not be required to submit this data beginning January 2021. CMS states it is unable to remove the item sooner, secondary to timelines associated with implemented changes to the Outcomes and Assessment Information Set (OASIS). **CHA supports this proposal.**

STANDARDIZED PATIENT ASSESSMENT DATA ELEMENTS

CMS continues implementation of requirements of the Affordable Care Act and the IMPACT Act, including development and implementation of quality measure domains using standardized data elements nested within patient assessment instruments. These changes are being implemented across all levels of post-acute care, including long-term care hospitals (LTCHs), inpatient rehabilitation facilities (IRFs), skilled-nursing facilities (SNFs), and home health agencies.

In the CY 2018 HH PPS proposed rule, CMS proposed requiring HHAs to report multiple SPADEs, but ultimately finalized only two. Commenters raised a general concern that CMS was moving too quickly and that further testing was needed. Since then, CMS has continued its assessment and evaluation, most notably by conducting a national beta test across the full care continuum, which included several providers in California. We appreciate CMS' efforts to provide additional opportunities for stakeholder communication and input, particularly the stakeholder webinar it held on November 27, 2018, to report on early findings of the test.

Beta Test Results

The beta test presents an important opportunity to test proposed SPADEs in real-world clinical settings and to obtain meaningful input from working clinicians and managers in post-acute care settings.

However, CHA continues to believe that the data's value is undermined by shortcomings in the investigation's scope and implementation. These significant limitations underscore the need to proceed carefully and thoughtfully with ongoing SPADE implementation, review, and modification.

Provider Sample

Although CMS took steps to recruit a number of providers and settings in several geographic areas, CHA continues to have concerns about whether the provider sample is representative of the larger community and types of patients cared for by HHAs. While all HHAs are subject to the same requirements, organizational distinctions are pertinent to the patient populations served and must be considered when evaluating results of the data.

For example, it is unclear whether *any* hospital-based HHAs were included in the sample. As compared to free-standing HHs, HHAs operated by hospitals or health systems see patients of greater medical complexity and/or with a wider range of socioeconomic needs, reflective of the local community. We

are similarly concerned about the lack of participating HHAs in rural areas. Rural HHAs serve an essential role in their communities and face unique operational challenges. The implications of these significant new data collection requirements in rural HHAs require additional review.

CHA expressed similar concerns in the context of the IRF, SNF, and LTCH PPS proposed rules. We understand and appreciate CMS's acknowledgment of this concern as well as its description of the sampling design. We also recognize and agree that, in the context of the primary beta test objective of assessing cross-setting use, the number of providers representative of each setting may not need to fully align with the actual proportion of that provider type in the US. However, regardless of sample size, CHA believes it is essential that the participants include a range of provider types, including both hospital-based vs. free-standing HHAs, and agencies serving both urban and rural communities.

Finally, CHA is also concerned about lack of sufficient information on diagnostic case mix or range of functional impairment of assessed beneficiaries. Absent this important information, the reader is unable to determine if this group is representative of the HH patient population at large, and — if not — how that selection may have affected the assessment process and results. **For all these reasons, CHA urges CMS to release a data set so that independent parties can further examine the sample characteristics and the data collected.**

Communicative and Cognitive Factors

As stated in CHA's previous PAC PPS comments, CHA member providers at all levels expressed concerns about patients with significant communication and cognitive impairment, who comprise a significant portion of PAC admissions and require significantly different — and frequently greater — intervention and resources than patients with physical deficits only.

We agree with CMS' statement that the national beta test did not explicitly exclude patients who were non-communicative, as those patients were subject to observational assessment for some items. However, this distinction does not recognize that PAC patients vary greatly in their communicative and cognitive abilities, and may have impairments ranging from mild to severe. Many individuals are not identified as non-communicative and are able to participate in an interview, but have mild to moderate deficits in communication or cognitive ability that will affect the accuracy of their responses, often in ways that is not clear to the interviewer. **CHA remains concerned that the beta test did not sufficiently include or account for the impact of such impairments in the assessment process, including their implications for administration and their impact on the integrity and validity of the data collected.**

Some patients with limited communication or cognitive skills may be under-represented in the data set, and this will present the agency with many challenges on a go forward basis. While we understand that the original beta test sampling design was to be inclusive of all qualifying patients in a participating setting, we received reports that, at times, patients who were "difficult" to assess were skipped or eliminated from the sample. **We recognize that our information on these instances is limited; however, we believe it is important to share with CMS the provider perception that patients with impairments who made assessment more difficult or time-consuming were excluded. If accurate, that exclusion has significant implications for the beta test conclusions and measure implementation.**

Assessing patients with communication or cognitive impairments simply takes longer, due to the need to provide necessary accommodations and validate responses. The omission of these patients from the

beta test undermines our ability to draw conclusions about the measures' applicability for the broader HHA population, such as how long the proposed assessment measures will take to complete in this setting. **Because CMS does not address if/how the measures or their administration can be modified, we question CMS' conclusions about their overall validity and reliability.**

Even among PAC patients who are able to participate in the interview questions, many will have mild or moderate deficits in communication or cognition that will affect their ability to respond accurately, and the lack of accuracy may not be readily apparent to the evaluator. While we note that representatives of CMS and the RAND Corporation acknowledged this serious concern in the November 27, 2018, stakeholder call, we do not believe that this critical concern has been sufficiently addressed in CMS' proposals for measure implementation and ongoing evaluation.

It is critical that the next steps in SPADE implementation consider the limitations of the currently available data. **We reiterate our request that CMS develop and implement a process to assess the value of specific indicators for all patient types on an ongoing basis.**

We also support and appreciate CMS' effort to make available the data set through the planned creation of research identifiable files. Allowing all parties access will lead to a richer and more informed policy discussion going forward. Releasing the data set will benefit CMS because, through additional third-party analysis, stakeholders will be able to more fully understand the potential impact on their organizations, leading to more informed and robust comments, and offer additional analysis for consideration.

New Proposed SPADEs

CMS proposes the implementation of several new, non-tested SPADEs and a new assessment domain. The new SPADEs include indicators designed to address use and indications of high-risk drug classes, interference of pain with therapy and activities, and several directed at collecting information on social determinants of health.

CHA supports and applauds CMS' recognition of the impact of social determinants of health (SDOH), as well as its efforts to implement a data collection process for social risk factors. However, as stated in prior comment letters, we are concerned that CMS plans to implement untested data elements. The lack of an adequate pilot or trial denies all stakeholders, including CMS, the ability to determine whether the new measures are accurate and valuable or identify the operational implications of their implementation. We appreciate that CMS has committed to a process that will provide transparency for future policy development in this area, including solicitation of stakeholder feedback. We look forward to engaging in that process.

Operational Implications

The current proposal represents a significant increase in the data collection and reporting requirements for HHAs. The actual time and cost impact of these new requirements will be considerably higher than CMS estimates. Moreover, anecdotal reports from beta test participants reveal a disconnect between stated policy and actual processes.

California post-acute care provider beta-test participants report that the time reported by the contractors to assess patients was not reflective of their experience. Due to the previously discussed

limitations in beta test patient sampling, the time and costs associated with administration for the full PAC population are grossly understated. Simply put, it is less time-consuming and less costly to administer these items to a cognitively intact, English-speaking patient with no speech or language deficit than to one with aphasia, attention and memory disorders, or whose primary language is not English. That shortfall, combined with the addition of several new indicators, renders CMS' estimate of the impact on providers' time and resources woefully inadequate.

As discussed in the November 2018 stakeholder call, a fruitful area of continued analysis would be the comparison of the results of the beta test items with similar items in the current patient assessment instruments and other medical documentation. Such a comparison would provide an additional "check" of whether the patient's response was accurate and reflective of their function and condition outside of the interview process.

In recent final rules, CMS noted that, "Contrary to what one commenter noted, we wish to clarify that time-to-complete estimates from the National Beta Test included the time spent both to collect data, including the review of the medical record, if needed and to enter the data into a tablet." This statement is not consistent with reports from some beta test recipients, who reported that they were directed to record input time only.

Recommendations

CHA and its member hospitals, who 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 HH payment system with patient characteristics and resource needs. On behalf of our member organizations, CHA has been actively engaged in supporting implementation of the IMPACT Act and stands ready to work with CMS as the transformation of PAC services payment and delivery proceeds. In that context, we would like to reiterate recommendations previously submitted in response to the IRF, SNF, and LTCH PPS proposed rules:

- 1. Modify the speed and scope of SPADE implementation.**

Over the past few years, data collection requirements for all post-acute care providers, including HHAs, have increased significantly, and members have experienced challenges in developing new procedures for coding, workflow, and documentation. The continuous and rapid pace of additions and changes limit HHAs' ability to make comprehensive changes or to identify the most effective and efficient way to meet new requirements. Absent a more gradual, considered timeline for implementation, HHAs are forced to continuously add new elements and processes to ones that already exist, without time to assess and test a re-designed workflow process that could more efficiently and effectively meet the goals of an accurate assessment and inter-setting communication.

This rapid change also affects the ability of HHAs and their partners to integrate with the electronic medical record. While our hospital members report that they actively collaborate with software vendors and information systems professionals, they note that this iterative process may lag behind the facility's need for actual implementation, so that providers are forced to develop inefficient and duplicative procedures. 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.

CHA supports the implementation of SPADEs, and based on the recently issued final rules, we understand that CMS plans to move forward with all of the proposed SPADEs, with limited modifications, in FFY 2019. However, we continue to urge CMS to consider modifying implementation in ways that will lessen provider burden, and lay the groundwork for effective and accurate data collection. For example, CMS could proceed with implementation and include a grace period, during which time PAC providers would be able to develop the operational procedures and work with EHR providers and others to develop efficient and more cost-effective processes.

- 2. Create and make transparent a data use strategy and analysis plan for the SPADE items so post-acute care providers, including HHAs, better understand how the agency will further assess SPADEs' adequacy and usability in the development of a unified PPS and future quality measures.** Data collection without an understanding of future use or subsequent analysis of performance based on the intended use is costly to our health care system. Interim alternatives should be strongly considered.

While the beta test was important, more work must be done to ensure that the SPADEs requested on the patient assessment tools can be put to good use in the development of our goals. We urge CMS to engage with stakeholders in detailing how it intends to use these data. We look forward to the forthcoming reports on findings of the national beta test and appreciate CMS's plans to create research-identifiable files.

We appreciate CMS's response, as expressed in recently issued PAC PPS final rules, to continue to monitor and evaluate SPADEs, and to engage stakeholders through future rulemaking. We continue to believe that this process will be more meaningful and effective if CMS took steps to proactively provide clear and transparent information about data use strategy, including how CMS will conduct ongoing assessment of SPADEs' utility outside of the formal rulemaking process. We believe that future rulemaking will benefit from a separate, robust, and focused review and analysis of SPADE data and implementation, to inform future specific policy decisions.

Data analysis should also include comparison of the results of the new SPADE items with similar items of other medical documentation, as discussed in the November 2018 stakeholder call. Such a comparison would provide an additional "check" of whether the patient's response was accurate and reflective of their function and condition outside of the interview process.

- 3. 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, and to allow time for providers to develop the necessary operational and workflow changes needed.**

A number of SPADE data elements could, as an interim strategy, be collected through claims analysis by the agency. We remain concerned that CMS has not considered any interim strategies to obtain data that are captured and coded to the Medicare claim. With such intense

focus on the SPADEs themselves, the idea of collecting similar information in an alternative format to inform the work prior to adding additional items on the IRF PAI has been lost. Before proceeding with full implementation, the agency should explain why certain data elements can only be obtained through the OASIS and other patient assessment tools, rather than through other means. This would help the agency prioritize and phase in implementation as appropriate.

Allowing voluntary reporting would enable CMS to use participating facilities as valuable “laboratories” for implementation that would provide support and guidance for other IRFs and inform CMS’ future work. It would also allow for the development of technological solutions that could support this process across all levels of care.

For example, several of the proposed elements relate to ongoing treatments or stable conditions that will be documented elsewhere in the patient’s medical record and will not change based on care setting or medical stability. As previously mentioned, some of this data may be obtained through claims analysis. Should that prove to be helpful, imposing a second step of voluntary reporting would allow providers time to work with their electronic health record vendors to develop systems that can populate these elements in the IRF-PAI without requiring additional assessment and documentation by the IRF. Several proposed elements would lend themselves to this approach, including many of the elements in the domain of special treatments and procedures (e.g., dialysis), impairments (e.g., hearing loss), and social determinants of health (e.g., ethnicity).

Following the development of a framework for prioritizing the SPADE elements, we ask that the agency lay out a multi-year plan for implementation. The current proposal for implementation by January 1, 2021, is not workable from an operational and IT infrastructure perspective. However, with additional time and shared understanding of future goals, providers can prioritize staff training and sequence IT resources to ensure smooth implementation of each of the prioritized data elements.

This multi-step approach would allow HHAs and CMS the opportunity to develop and manage their coding, assessment, and documentation procedures in a comprehensive and thoughtful manner, and it would provide more lead time to collaborate with key partners. Understanding how the data are intended to be used is critical to this process.

CHA appreciates the opportunity to comment on the CY 2020 HH PPS proposed rule. If you have any questions, please do not hesitate to contact me at akeefe@calhospital.org or (202) 488-4688; or my colleague Pat Blaisdell, vice president continuum of care, at pblaisdell@calhospital.org or (916) 552-7553.

Sincerely,

/s/

Alyssa Keefe

Vice President Federal Regulatory Affairs