January 4, 2016

Andy Slavitt  
Acting Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Hubert H. Humphrey Building  
200 Independence Avenue, Southwest, Room 445-G  
Washington, D.C. 20201

SUBJECT: CMS-3317-P. Medicare and Medicaid Programs; Revisions to Requirements for Discharge Planning for Hospitals, Critical Access Hospitals and Home Health Agencies Proposed Rule, November 3, 2015

Dear Acting Administrator Slavitt:

On behalf of our nearly 400 member hospitals and health systems, including acute and post-acute providers throughout the patient care continuum, the California Hospital Association (CHA) welcomes the opportunity to provide comments on the proposed rule outlining revisions to the Conditions of Participation (CoPs) for discharge planning for short-term acute care hospitals, critical access hospitals (CAHs), long-term acute care hospitals (LTCHs), inpatient rehabilitation facilities (IRFs), inpatient psychiatric facilities (IPFs) and home health agencies (HHAs).

CHA commends CMS in taking action to address another important section of the CoPs for hospitals and other providers. Regulations governing hospitals and other providers must keep pace with the rapidly changing health care delivery system in order to ensure high quality and efficient care. Moreover, appropriate oversight must be balanced with the need for flexibility and innovation. The proposed revisions to the CoPs and subsequent interpretive guidance should move us forward in achieving our shared goals for patient engagement, as well as other goals outlined in the National Quality Strategy, without creating duplicative processes and administrative burden.

CHA supports policies and practices for effective and sustainable transitions of care, and commends CMS’ efforts to update existing CoPs to align with current practices and to clarify expectations for providers. However, we have concerns about some of the specific changes proposed and their impact on both facility/organization operations and patient care.

In summary, CHA urges CMS to:

- Allow one year between the release of the final rule and the effective date for implementation.
- Provide flexibility to hospitals in the design and implementation of their associated policies and procedures.
- Limit administrative burden and additional unnecessary costs to the health care system by allowing hospitals to develop a process to identify specific high-risk patients for whom a discharge requiring evaluation and development of a discharge plan is necessary, rather than assume a one size fits all approach.
• Eliminate the requirement to begin the discharge plan within 24 hours, and instead require that discharge plans be developed on a timely basis, as appropriate to the patient’s condition and the setting of care, and in advance of the patient’s discharge to home or to the next setting of care.

• Clarify in the final regulations that care planning and discharge disposition, including level of care determinations, are made based on a clinical assessment of the individual’s medical and functional status as appropriate and medical necessity for continued care.

• Take a comprehensive look at the current process for development, implementation and evaluation of the CoPs, as well as surveyor and provider education, and make necessary changes that will encourage shared understanding of expectations across all settings.

Our detailed comments on the proposed discharge planning changes, as well as general comments on the survey and certification process, are noted below.

**DESIGN**

The proposed standards would require the discharge planning process policies and procedures to be:
(1) developed with input from the hospital’s medical staff, nursing leadership and other relevant departments; (2) reviewed and approved by the governing body; and (3) specified in writing.

CHA agrees that discharge planning policies and procedures should be developed with adequate input from medical staff and clinical leadership and be specified in writing, and that policies should be subject to adequate oversight by organizational leadership. However, hospital and health system governance structures vary and continue to change as healthcare transformation proceeds. **CHA urges CMS to allow flexibility in the regulatory language to allow for either the governing body or an equivalent leadership body inclusive of the medical staff to approve these policies.**

**APPLICABILITY**

Currently, federal regulations require hospitals to have a process to ensure identification of inpatients for whom a discharge plan is necessary, but do not necessarily require that a discharge plan be developed for all patients. Under the provisions of the proposed rule, hospitals would be required to provide specific discharge instructions for:

- All inpatients;
- Outpatients receiving observation services;
- Outpatients undergoing surgery or other same-day procedures for which anesthesia or moderate sedation is used;
- ED patients identified by the ED practitioner as needing a discharge plan; and
- Any other category of outpatients as recommended by the hospital’s medical staff and specified in hospital policies and procedures.

We understand and agree with CMS’ goal that all patients leave the hospital with adequate preparation. However, we believe that the requirement as proposed is too broad, increases unnecessary costs and requires additional clarification.

**First, CHA urges CMS to distinguish between the development of a comprehensive discharge plan and the provision of appropriate discharge instructions, and to provide hospitals flexibility in the design and implementation of their policies and procedures associated with developing and furnishing both.** We believe there is an important distinction between a comprehensive discharge plan
and the provision of appropriate discharge instructions that will enable our member hospitals and other providers to direct limited resources and time where they are most needed.

A discharge plan begins with a comprehensive assessment of patient goals and preferences, diagnosis and comorbidities, functional ability, patient resources, and caregiver availability. The results of this assessment will drive the planning process for post-hospital care. This level of comprehensive evaluation is essential for inpatients with complex medical needs, chronic conditions and/or significant functional impairment. For example, an elderly individual who has suffered a stroke may need extensive planning for ongoing medical care, rehabilitation services and, if being discharged to home, training for family members or caregivers to support the patient’s continued medical recovery and safety.

By contrast, many other patients admitted for a specific procedure or process will require significantly less intense planning. Requiring the development and documentation of a full evaluation and comprehensive plan is unnecessary. For example, an individual who is admitted for an elective surgical inpatient procedure will appropriately receive instructions specific to the procedure he/she underwent, but would not necessarily derive additional benefit from more extensive evaluation. For these patients, hospitals have already developed policies and procedures to ensure that appropriate discharge instructions are provided. This would not preclude the hospital from creating policies and procedures for physicians or other members of the patient care team to identify a patient in need of a more comprehensive planning process; if that were the case, the more comprehensive process would begin. We urge CMS to clarify the regulatory language that would allow for appropriate identification of inpatients for a comprehensive discharge plan.

CMS should ensure that all inpatients receive the level of discharge planning or instructions that meets their needs, without creating additional burdensome and costly requirements. Overall, hospitals would continue to be responsible to identify those patients who require a more extensive planning process, including the initiation of a comprehensive discharge planning assessment and plan, while ensuring that others receive adequate discharge instructions for the condition for which they are being treated.

Therefore, CHA urges CMS to limit the requirement for a documented discharge plan or instructions to all individuals admitted as inpatients, and modify the requirements for outpatients as detailed below. We believe the number of patient populations impacted by the proposed rule is overly broad, unnecessary, and will add significantly to the cost of care for hospital-based services.

Outpatient Visits
Many outpatient visits and same day procedures are, by their very nature, limited in scope and duration. For routine or discrete events, such as a colonoscopy or an emergency department visit for a minor injury, standardized patient instructions for post-procedure care are appropriate, efficient and effective. Hospitals could reasonably be expected to have procedures in place to provide standardized discharge instructions for most patients, while ensuring that more complex patients are identified for additional assessment and planning, as mentioned above.

In addition, CHA is concerned that the proposed inclusion of same day surgery or procedure patients would effectively result in inconsistent standards between patient care settings, and would require higher costs for the hospital setting as compared to ambulatory surgery centers or urgent care centers. We believe that standards and requirements for similar patient care activities, including requirements for discharge instructions, should be standardized across all patient care settings. Therefore, CHA recommends that same day surgery and procedure patients, as well as all other outpatients, be
excluded from the current proposed requirements unless otherwise identified through the risk assessment process as noted below.

For all other outpatients — including observation patients, patients receiving surgery or procedures with anesthesia or moderate sedation, patients seen in the emergency department and others — we urge CMS to adopt a policy requiring hospitals to develop a process by which they can identify patients for whom a more discharge needs evaluation and development of a discharge plan is necessary, rather than to assume a one-size-fits-all approach to discharge planning.

CHA suggests that CMS adopt language similar to language in CFR 482.43, which currently applies only to inpatients:

The hospital must have in effect a discharge planning process that applies to 1) outpatients receiving observation services, 2) outpatients undergoing surgery or other same day procedures for which anesthesia or moderate sedation are used, 3) emergency department patients identified in accordance with the hospital’s discharge planning policies and procedures by the emergency department practitioner responsible for the care of the patients as needing a discharge plan, and 4) any other category of outpatients as recommended by the medical staff and specified in the hospital’s discharge planning policies and procedures approved by the governing body or an equivalent leadership body inclusive of the medical staff.

(a) The hospitals must identify as soon as possible after registration all patients in the categories above who are likely to suffer adverse health consequences upon discharge if there is no adequate discharge planning.

(b) The hospital must provide a discharge planning evaluation to the patients identified in paragraph (a) and to other patients upon the patient’s request, the request of a person acting on the patient’s behalf, or the request of the physician.

INITIATION OF PLAN

Under the proposed rule, hospitals would be required to begin identification and documentation of the anticipated discharge needs for each applicable patient within 24 hours after admission or registration. The process would be completed prior to discharge home or transfer to another facility and without unduly delaying the patient’s discharge or transfer. The same standards would apply if the patient’s stay was less than 24 hours. CMS notes that this policy would not apply to emergency-level transfers of patients who require a higher level of care.

CHA supports the development and modification of a discharge plan as soon as possible for all inpatients, but believes that the 24-hour deadline is arbitrary, unrealistic, and inconsistent with effective clinical practice.

A specific 24-hour deadline limits the provider’s flexibility to address a patient’s individual condition and care needs. For many patients, initiating discharge planning immediately upon admission is not possible, because their clinical and functional status is rapidly changing and additional evaluation and treatment is needed to identify post-hospital needs. When first admitted, patients and families are often in the midst of dealing with the onset of a serious medical illness or a sudden traumatic event, and may not be able or open to engage in discussions about post-hospital care and resources. Some patients and family will even resist such discussions for being intrusive or premature.
In some settings, initiation of a discharge needs assessment and planning within 24 hours is inconsistent with current care planning requirements. For example, patients admitted to an IRF or LTCH undergo evaluations within the first few days of care. The goals of this evaluation process are to ensure assessment by multiple disciplines and the associated interdisciplinary coordination of care, and to identify short and long-term care needs to aid treatment and discharge planning. For example, in the IRF setting, CMS regulations provide for the completion of the overall individual interdisciplinary plan of care within 4 days of admission. To require documentation of a needs assessment within 24 hours would be duplicative and clinically meaningless.

CHA urges CMS to eliminate the requirement to begin the discharge plan within 24 hours, and instead require that discharge plans be developed on a timely basis, as appropriate to the patient’s condition and the setting of care, and in advance of the patient’s discharge to home or to the next setting of care.

**COMMUNICATION WITH PRACTITIONER**

CMS proposes that hospitals be required to send a copy of the discharge summary within 48 hours of the patient’s discharge and pending test results within 24 hours of their availability.

CHA agrees that timely communication of clinical information is important to the discharge and transition planning process. However, we believe that the language for this provision should be modified to reflect and accommodate current practice, including circumstances where an electronic medical record is available to practitioners throughout the continuum of care. We recommend that the proposed term “send” be replaced with or supplemented by the addition of “make available.” This term is most appropriate when discussing use of an electronic health record.

Additionally, we urge that CMS change the requirement for communication of pending test results within 24 hours of “availability,” and allow for a longer interval for routine test results. In some cases, test results may be complete and “available,” but are subject to additional review by the ordering practitioner — who may reasonably take longer than 24 hours to review — before the hospital may release them to other providers. Moreover, state law prohibits some patient tests from being released until after physician review. In cases where the test results do not significantly impact the care plan, a window of 48 hours is more feasible and will not compromise patient care.

The proposed rule makes no mention of the current processes and objectives laid out in meaningful use regulations, despite the fact that some stage 2 and stage 3 objectives conflict with the current language. CHA urges CMS to allow for flexibility, but to look for alignment between the standards. Moreover, CHA supports the detailed comments submitted by the American Hospital Association regarding the alignment with both Meaningful Use and the care transitions quality measures for inpatient psychiatric facility quality measurement requirements.

**MEDICATION RECONCILIATION**

Medication reconciliation is an important component of safe and sustainable care transitions, and we applaud inclusion of specific requirements for this process in the discharge planning requirements. However, **CHA recommends that the checking the Prescription Drug Monitoring Program (PDMP) database should remain an optional component of the discharge planning process.**
We are concerned about CMS’ consideration of a requirement to consult with the state PDMP database, which would be an unnecessary step for most patients and would slow down the discharge process. Moreover, access to the data base is limited to certain authorized users. In some settings, the individual who is directly responsible for the development of the discharge plan may not have direct access to the PDMP, and coordinating with other practitioners will be impractical and unnecessary. Rather, consultation should occur on a case-by-case basis, determined by factors identified in the medication reconciliation or medical history.

We have concerns that California’s PDMP system is not prepared to handle the number of database inquiries or provider registrations created by this requirement. Additionally, interoperability challenges of PDMPs have not been addressed.

**FOLLOW-UP PROCESS**

For patients discharged to home, hospitals would be required to establish a post-discharge follow-up process. CMS does not propose a specific mechanism or timing for the follow-up process, but encourages hospitals to use innovative, low-cost post-discharge tools and technologies where health care providers and caregivers can ask simple questions to identify individuals at risk for readmissions.

CHA agrees that adequate follow-up after a transition of care is a valuable process. By providing essential support to individual patients following a hospital stay, medical providers can support a patient’s continued recovery and avoid unnecessary problems, including readmissions.

Some patients are at higher risk for re-hospitalization than others, based on clinical factors such as the presence of certain chronic conditions or comorbidities of functional impairments. Many hospitals have developed processes to identify such high-risk patients. Additionally, many patients receive post-hospital care coordination from other entities such as a medical group, health care plan or a home health agency. Receiving multiple calls from the acute care hospital and other entities regarding ongoing care coordination can be confusing and disruptive to the patients and caregivers, and does not improve overall care planning, implementation or outcome.

We believe that the follow-up is process is most valuable when targeted to those patients who are most at risk and to those who may not receive care coordination services through another entity, rather than to all patients on a routine basis. Under this system, hospitals will be able to dedicate their resources to meaningful intervention and support to those who can truly benefit.

**CHA supports the proposed requirement that hospitals implement a post-discharge follow-up process. CHA recommends that CMS provide for flexibility and latitude in the design of such processes, so that hospitals can develop and implement processes that best meet the needs of their patients and communities.**

**SELECTION OF POST-ACUTE CARE PROVIDER**

The proposed rule includes a new requirement for hospitals and home health agencies to assist patients and their support persons who are transferred to a post-acute care provider — including an IRF, LTCH, SNF or HHA — in selecting a provider by using data that includes IRF, LTCH, SNF, or HHA standardized patient assessment data, data on quality measures, and data on resource use. CHA supports informed decision-making and the provision of information to patients/residents to support their care decisions and provider selection. In this context, we appreciate CMS’ statement that the facility
must ensure that this data is relevant and applicable to the resident’s goals of care and treatment preferences.

Care planning, including discharge planning from the hospital setting and selection of a post-acute care provider, is a complex process that includes consideration of multiple factors such as medical status, prognosis, and patient resources and preferences. An individual patient’s course of recovery and long-term outcome are not readily predictable from a defined set of data points collected during an acute stage of illness. Recovery trajectories and outcomes vary widely, even among patients who appear similar at a specific point in time. Assessment of patient characteristics may provide valuable information for short-term care planning but may not be predictive of ultimate outcome or future care needs.

Similarly, the use of certain quality measures in planning discharge disposition is problematic, as many do not provide meaningful information to patients and others unfamiliar with existing measures and their limitations. For example, we have previously expressed concerns to CMS about the challenges of the SNF 5-star ratings, in particular the limitation of certain quality indicators for specific post-acute populations (e.g., reporting pain post-orthopedic surgery). CHA does not oppose sharing data provided by CMS to help inform the patient decision-making process. However, we believe that additional explanation will be required, as this information may be confusing to patients. **CHA urges CMS to detail what data needs to be provided to patients and to develop materials (discussion guides and or consumer friendly informational material) that hospitals and other providers can use to help explain this information to patients.**

Further, CHA strongly asserts that care, placement, and discharge planning decisions should continue to be clinician-driven and based on a clinical assessment of the individual patient’s medical and functional status. Great care is taken to address the patient goals, needs and wishes. Data elements collected via a standardized patient assessment process will be a valuable tool to inform the care planning process at all levels, but care should be taken to prevent its use as the determining factor in patient access to medically necessary care. **CHA strongly recommends that CMS clarify in the final regulations that care planning and discharge disposition, including level of care determinations, are made based on a clinical assessment of the individual’s medical and functional status and medical necessity for continued care, in full consideration of the patient goals, needs and wishes.**

**Behavioral Health Needs**

CHA agrees with CMS’ comments on the advantages of considering the needs of psychiatric and behavioral health patients when planning discharge. We are concerned, however, about the impact of current limitations in available home and community-based services and skilled nursing facilities that can care for individuals with behavioral health needs. CHA member hospitals report significant difficulty securing appropriate post-hospital care for patients who no longer require a hospital level of care, but have mental or behavioral health issues requiring continued care, including residential care. These patients remain in hospital beds beyond the time required to treat their medical condition, often for extended periods — weeks, months, or even years. Keeping such patients in the hospital setting compromises patient outcome and diverts costly and valuable resources. Steps must be taken to address the critical shortage to psychiatric and behavioral health services so that care can be delivered at the right time and in the right setting.

**CHA applauds CMS’ increased focus on behavioral health services. However, we remain concerned about the numerous reports from our member hospitals that they are unable to access post-hospital care meeting the behavioral health needs of their patients. We urge CMS to work closely with**
stakeholders — including hospitals, SNFs, home and community-based programs, state Medicaid programs and health plans — to identify and develop additional programs and services to meet patient needs, and to facilitate timely access to care for our most vulnerable beneficiaries.

**EFFECTS ON PROVIDERS**

CMS notes that its estimates of the effects of the proposed regulations are subject to significant uncertainty. Moreover, we believe CMS significantly underestimates the costs associated with implementation. One example among many is the costs associated with medication reconciliation as one of the important aspects of discharge planning. In the proposed rule, CMS notes “We estimate that this activity would require an average of 3 minutes for each patient or 0.05 hours. We estimate that there are about 600,000 discharges annually that would require this medication reconciliation. Nurses earn an average hourly salary of $67. Thus, complying with this requirement would require an estimated 30,000 burden hours (600,000 discharges × 0.05 hours per patient) across all CAHs annually at a cost of $2 million (30,000 burden hours × $67).”

CHA member hospitals point to recent studies and evidence that to ensure accuracy and safe care transitions; medication reconciliation takes 20-30 minutes. The estimate of 3 minutes for average time of medication reconciliation is inaccurate and would not be sufficient to perform this function accurately and safely. We urge CMS to consider these studies and others in understanding the time and resources needed to appropriately and safely discharge patients.

It is also important to note that the cost estimate noted above is limited to CAHs, and CMS does not address the associated significant impact on costs and resources across all hospitals. In California, a total of 2.5 million inpatients are discharged from acute care hospitals to home, and an additional 300,000 are sent home with home health services. If each of these discharges were to receive a 20 minute medication reconciliation, complying would require a minimum estimated 924,000 burden hours (2.8 million discharges x .33 hours) across all CA hospitals annually, at a cost of greater than $61 million (924,000 burden hours x $67).

CMS estimates that some portion of entities’ costs will be recovered by other third-party payments, as hospitals periodically revise their charges to private insurance carriers, which can partially offset cost increases for the approximately half of all patients who are “private pay.” **CHA strongly disagrees with CMS’ assumptions and assertions regarding the effect of the proposed rule on providers.** Implementation of the requirements as written, particularly the initiation of a plan within 24 hours of admission/registration for all inpatient and several categories of outpatients, will require significant increases in staffing in our member hospitals and, as discussed in these comments, will not necessarily result in improved patient care outcomes. **At a time when hospitals and other providers are working to streamline patient care processes and to reduce costs, it is essential that new requirements be designed and scaled in a way that will preserve clinical and operational value without adding redundant or unnecessary procedural or documentation requirements.**

We are also concerned about CMS’ assumption that costs would be offset by private pay providers, who CMS estimates as half of all patients. Many of our hospital members serve primarily Medicare and Medicaid beneficiaries, as well as many undocumented and uninsured individuals and have very limited – far less than half — numbers of private pay patients. This is particularly true for our rural and critical access hospitals, as well as for safety net hospitals located in urban areas. Not surprisingly, these same facilities serve some of the most complex and challenging patients who may have limited resources to
support discharge planning. These facilities, and many others, do not have the payer mix to balance the increased costs associated with compliance with the new regulations, as CMS suggests.

The proposed rule will take significant time and resources to implement, and we urge CMS to scale its proposed processes as appropriate. CMS must continue to think about how hospitals are innovating and using tools to identify our most at-risk patients, rather than once again propose a one-size-fits-all approach with rigid standards that limit flexibility and add significant costs to our health care system.

**Hospitals and other providers understand and share CMS’ goals for discharge planning and follow up.** However, as institutions committed to delivering high-quality affordable care, we wish to be held accountable for the outcomes of our innovative processes, rather than be burdened with cumbersome and narrowly defined processes.

**COPs Development and Implementation Recommendations**

In addition to the detailed comments and proposed revisions to the specific CoPs noted above, CHA encourages CMS to look closely at the current process for development of the CoPs, interpretive guidance, survey training and provider education. Our recommendations include:

- **Engage stakeholders early in the process, and throughout the entire process.** CHA appreciates the important role the formal rulemaking process provides. However, the CoPs, unlike other CMS initiatives, have neither a formal process for seeking early input for changes nor a formal process for surveyor or provider education following the release of new interpretative guidance. Information about changes in the CoPs or interpretive guidance is currently shared through memorandums to state survey agencies on a periodic basis. Changes in the CoPs and interpretive guidance stand in stark contrast to the roll out of CMS’ two-midnight rule, for which CMS sought early input on addressing the issue of short stays in 2013 (through the rulemaking process), hosted multiple national provider calls and contracted with both Medicare administrative contractors and quality improvement organizations to educate providers on this policy. While the policy is still applied somewhat inconsistently, it is much more consistent than the variation we see across the state of California in the survey and certification process. CMS should consider a number of improvements to such an important aspect of Medicare program policy.

- **Ensure transparency in development of interpretive guidance.** CHA has provided very specific recommendations to the proposed regulation and applicable requirements noted above. However, the final rule is only the first of many critical components required to promote clear and concise interpretation and application of the CoPs nationwide. The interpretive guidance that will subsequently be developed is critical to the appropriate evaluation of hospitals and other providers. CHA urges CMS to engage both state survey agencies and the provider community in soliciting input through a sub-regulatory process, allowing for a 30-60 day comment period prior to finalization of any interpretive guidance. The proposed rule raises a number of unanswered questions, and such a process would help to facilitate shared understanding of expectations going forward.

- **Additional resources and training for CMS regional offices and state surveyors.** CHA urges CMS to provide 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, failing to meet the needs and keep pace with the changing nature of the delivery of care. Lack of education and a formal process for surveyor evaluation leads to inconsistent interpretation of the CoPs from state to state, and often within California. This
reinterpretation and inconsistency across state, regional and federal agency staff adds costs to the health care system, as well as undue stress and uncertainty for providers who are making every effort to follow the rules as they understand them.

- **Engage in continuous process improvement strategies.** CHA strongly encourages CMS to take several steps to improve the Medicare State Survey and Certification process to improve provider and surveyor understanding of the CoPs and interpretive guidance. Webinars through various national associations are not appropriate means for provider education. Similar to the LEAN process undertaken by CMS to address quality measurement development and implementation strategy within the agency, CHA urges CMS to consider a LEAN process improvement strategy as it develops, adopts, implements and evaluates all changes to the CoPs and interpretive guidance going forward. Hospitals and other stakeholders wish to be engaged in this process. CHA sees multiple opportunities for improvements going forward and stands ready to work with CMS on this important endeavor.

**PHASE-IN IMPLEMENTATION**

Overall, we support CMS’ efforts to modernize and update the requirements. However, the scope of the proposed changes is extensive. Hospitals and other providers will be challenged to develop processes to clearly demonstrate their compliance without additional clarity provided by CMS. This will significantly impact resources, including staff time for development and implementation of new documentation procedures.

We urge CMS to phase-in implementation of new requirements one year from the effective date of the rule to allow for the development of new systems, changes to the EHR and personnel training. Notably, CMS should consider year one as a pilot year to further educate providers and continually evaluate the interpretive guidance as needed.

CHA appreciates the opportunity to provide our input on the proposed rule. If you have any questions, please contact Pat Blaisdell, CHA vice president, continuum of care, at pblaisdell@calhospital.org or (916) 552-7553, or me at akeefe@calhospital.org or (202) 488-4688.

Sincerely,

/s/
Alyssa Keefe
Vice President Federal Regulatory Affairs

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