November 16, 2018

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3346-P
Submitted electronically to: http://www.regulations.gov

Re: Medicare and Medicaid Programs; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction

Dear Administrator Verma:

On behalf of the Premier healthcare alliance serving approximately 4,000 leading hospitals and health systems, hundreds of thousands of clinicians and 165,000 other provider organizations, we appreciate the opportunity to submit comments regarding the proposed rule Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction. Premier healthcare alliance, a 2006 Malcolm Baldrige National Quality Award recipient, plays a critical role in the rapidly evolving healthcare industry, collaborating with members to co-develop long-term innovations that reinvent and improve the way care is delivered to patients nationwide. Additionally, Premier maintains the nation's most comprehensive repository of hospital clinical, financial and operational information and operates one of the leading healthcare purchasing networks. Our comments primarily reflect the concerns of our owner hospitals and health systems which, as service providers, have a vested interest in the implications of Federal regulations.

Premier appreciates CMS' thoughtful approach to resolving redundancies in the Conditions of Participation (CoP) by simplifying or eliminating the unnecessary burden currently placed on providers. We are generally support the proposals in this rule and are pleased that CMS continues to demonstrate its commitment to reducing unnecessary regulatory burden and costs for hospitals, critical access hospitals (CAHs) and ambulatory surgery centers (ASCs).

QUALITY ASSESSMENT AND PERFORMANCE IMPROVEMENT PROGRAM

In prior rules, CMS adopted policies that allows, but does not require, one governing body to oversee multiple hospitals in a multi-hospital system and allow each hospital that is subject to a common system governing body to voluntarily have a unified and integrated medical staff. Now, CMS is proposing that the system governing body legally responsible for a hospital system consisting of two or more separately certified hospitals could elect to have a unified and integrated Hospital Quality Assessment and Performance Improvement (QAPI) and infection control programs for all of its member hospitals after determining that such a decision is in accordance with all applicable State and local laws. Each separately certified hospital subject to the system governing body would have to demonstrate that the unified and integrated QAPI program:

- Is established in a manner accounting for each member hospital's unique circumstances and any significant differences in patient populations and services offered in each hospital, and
- Establishes and implements policies and procedures to ensure that the needs and concerns of each of its separately certified hospitals, regardless of practice or location, are given due

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consideration, and that the unified and integrated QAPI program has mechanisms in place to ensure that issues localized to particular hospitals are duly considered and addressed.

We support the proposal to allow multi-hospital health systems to have unified infection control programs and QAPI programs for all hospitals in the system. We appreciate that CMS allows each health system to decide the best approach to quality assessment.

HISTORY AND PHYSICAL

Current regulations require that a history and physician (H&P) must be completed and documented for each patient no more than 30 days before or 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services. An updated examination of the patient, including any changes in the patient's condition, must be completed and documented within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services, when the H&P are completed within 30 days before admission or registration. ASCs and hospital outpatient departments (HOPDs) have expressed concerns related to the significant burden of requiring a comprehensive H&P for the volume of minimally invasive surgical procedures that are performed under minimal sedation or local anesthesia.To address this feedback CMS proposes that a provider performing a procedure in a HOPD or an ASC can exercise their clinical judgment to identify specific patients not requiring a comprehensive H&P prior to specific outpatient surgical or procedural services, and instead require only a pre-surgical assessment.

Premier supports giving hospitals and ASCs the flexibility to establish a medical staff policy that describes when a pre-surgery/pre-assessment could be used instead of a comprehensive H&P. We believe the proposal will allow clinical staff more time for patient care, enable patients to schedule procedures sooner without the need of a primary care visit and reduce expenditures for potentially unnecessary pre-operative testing that is performed simply because it is required by policy without any benefit to the patient. In addition, **CMS should maintain deference to provider in medical judgement with regards to identifying patients of lower risk and ensure that any procedure for physician sign off of pre-surgical assessment not add any additional burden.**

EMERGENCY PREPAREDNESS

In September 2016, CMS finalized a rule requiring facilities to have an emergency preparedness program that includes: risk assessment and emergency planning, policies and procedures, a communication plan, training and testing. In this proposed rule, CMS proposes several changes to reduce provider and supplier burden without undermining emergency preparedness. These include:

- Requirements for Emergency Plans: Hospitals would no longer need to document efforts to contact local, tribal, regional, state, and federal emergency preparedness officials related to their participation in collaborative and cooperative planning efforts.
- Requirements for Annual Review of Emergency Program: Providers would be required to review their emergency plan, policies and procedures, communication plan, and training and testing at least every two years rather than the annual commitment to do so that is currently in place.
- Requirements for Training: A training program for the emergency plan would have to be provided every two years rather than annually, after the initial training for the emergency program. Additional training would be required when the plan is significantly updated.
- Requirements for Testing: The types of acceptable testing exercises that may be conducted is expanded so one of the two annually required testing exercises may be an exercise of the

provider's choice. This could include one community-based, full-scale exercise, if available; an individual facility-based functional exercise; a drill; or a tabletop exercise or workshop that includes a group discussion led by a facilitator.

We support these proposals. Premier is pleased that CMS is providing flexibility for how institutions meet the emergency preparedness requirements.

CONCLUSION

In closing, the Premier healthcare alliance appreciates the opportunity to submit these comments on the Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction proposed rule. If you have any questions regarding our comments or need more information, please contact Aisha Pittman, senior director, payment and quality policy, at aisha_pittman@premierinc.com or 202.879.8013.

Sincerely,

Blair Childs
Senior vice president, Public Affairs
Premier healthcare alliance