December 24, 2013

Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–9954-P
7500 Security Boulevard
Baltimore, MD 21244–1850
(Sent electronically to http://www.regulations.gov)

Re: Patient Protection and Affordable Care Act: HHS Notice of Benefit and Payment Parameters for 2015 (CMS-9954-P)

Dear Ms. Tavenner,

On behalf of the more than 220 member children’s hospitals across the country, the Children’s Hospital Association (the Association) appreciates the opportunity to comment on the Health and Human Services (HHS) Notice of Benefit and Payment Parameters for 2015. Our comments focus on § 156.1110 Establishment of patient safety standards for qualified health plans (QHP) issuers and reflect our belief that quality and patient safety standards must reflect all of the populations, including children, served by QHPs and the hospitals with which they contract.

Patient Safety Standards--Hospital Size

§ 156.1110 (a) of the proposed rule codifies Section 1311(h)(1) of the Affordable Care Act (ACA), which specifies that QHPs may contract with hospitals with greater than 50 beds only if the hospitals meet certain patient safety standards. The agency seeks comments on whether the number of hospital beds should be adjusted to be greater or less than the standard under Section 1311(h)(1). The Association recognizes that smaller hospitals, especially critical access hospitals, have limited resources to adopt potentially burdensome safety requirements. However, we recommend that the Centers for Medicare and Medicaid Services (CMS) work with hospitals with 50 or fewer beds to consider the feasibility of instituting some minimum quality standard for these hospitals. Almost all of the Children’s Hospital Association’s members with 50 or fewer beds are accredited, either by The Joint Commission or by the Commission on Accreditation of Rehabilitation Facilities.
Two-year Time Frame for First Phase of Implementation

CMS is requesting comments on the proposed 2-year time period for the first phase of implementation of the patient safety standards for QHP issuers. We recommend that CMS evaluate how many hospitals nationwide already are developing a QAPI program and have in place a discharge planning process that applies to all patients to determine the appropriate time period for the first phase.

Requirements for Next Phase of Implementation

CMS also seeks comments regarding requirements that should be included in the second phase of implementation, including core aspects to be included in hospital patient safety programs, requirements for discharge planning programs, quality improvement activities that should be implemented, exceptions to patient safety standards, and how QHP issuers could effectively track patient safety information. In general, the Association believes it is critical that patient safety, discharge planning and quality improvement programs address all of the populations, including children, served by the hospital and QHP.

The Association believes that patient safety organizations (PSOs) play a critical role in helping hospitals improve patient safety through reporting, analysis, and data-sharing mechanisms and that PSOs should be an important component of a list of options on complying with requirements for using a Patient Safety Evaluation System. The Child Health Patient Safety Organization, a component of the Association, was established in recognition of the unique challenges of caring for the pediatric population. The Association supports and encourages hospital participation in PSOs and looks forward to working with HHS to facilitate pediatric provider participation in the most appropriate PSO or other patient safety vehicle that promotes safety and quality of children’s health care and reflects the objectives established in the National Quality Strategy.

The Association respectfully urges HHS to consider the following recommendations to ensure that patient safety programs do, in fact, meet the unique health care needs of children.

Core Aspects to be included in Hospital Patient Safety Programs: Hospital patient safety programs must be comprehensive, involve patients and families, and include appropriate expertise for the populations served by the hospital. Hospitals serving children must include pediatric expertise in the design, implementation and monitoring of their patient safety programs and ensure that safety guidelines developed for adult populations are appropriate for and/or are modified for children. For example, a system to ensure medication safety for children must include the capacity for weight-based dosing. A second example relates to safe practices to avoid catheter associated bloodstream infections. Pilot survey worksheets for the Infection Control Conditions of Participation related to central venous catheters reflect the importance of compliance with an insertion bundle. Compliance with a maintenance bundle has been
shown to be equally, if not more, critical in pediatrics in preventing catheter-associated bloodstream infections. (Miller MR, Niedner MF, Huskins WC, et al., 2010).

**Comprehensive Hospital Discharge Planning Programs**: The Association is pleased that the ACA recognizes the importance of a discharge planning program that applies to all patients. Comprehensive hospital discharge planning programs must reflect the needs of the populations (e.g., by age group) and sub-populations (e.g., by level of complexity) served by the hospital. Features of a comprehensive discharge planning program that may be more unique in hospitals serving children include the structure and function of the child’s family and social environment, ongoing coordination with other settings, such as schools, development of goals for the child following discharge, and recognition of the child’s developmental stage and milestones to be achieved.

**Health Care Quality Improvement Activities**: In general, the Association believes that hospital and plan quality improvement activities should be designed to address the aims set forth in the National Quality Strategy and that a comprehensive program should reflect the key domains of quality (safe, effective, efficient, equitable, timely and patient/family centered). Flexibility in identification and prioritization of activities according to the populations served by the hospital and plans and organizational performance should be allowed; however, quality improvement activities should be in place for all types of patients (newborns, children, adolescents, adults) served by the hospital. For example, involvement of parents is critical in ensuring that care is patient/family focused in pediatrics, Patients and families should be involved in the identification of priorities and in improvement activities.

**Considerations of Exceptions to Patient Safety Standards**: The Association recommends that the only exceptions to patient safety standards should be based on evidence that a particular standard is not appropriate for a specific group of patients. Additionally, there may be some (few) instances in which the adoption of a specific practice is unreasonably costly if the likelihood of an event is extremely low in the populations served by the hospital.

We appreciate the opportunity to provide input on this proposed rule. If you have any questions on our comments, please contact Ellen Schwalenstocker at 703-797-6045 or ellen.schwalenstocker@childrenshospitals.org.

Sincerely,

M. James Kaufman, PhD
Vice President, Public Policy