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Office of Health Affairs

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Center for Quality Improvement and Patient Safety
Attention: Patient Safety Act NPRM Comments
Agency for Healthcare Research and Quality
540 Gaither Road
Rockville, MD 20850

**RE: 42 CFR Part 3 Patient Safety and Quality Improvement Proposed Rules
(Federal Register Vol. 73, No. 29)**

Dear Sir or Madam:

On behalf of The University of Texas System, an academic system comprised of six academic health centers, including The University of Texas M.D. Anderson Cancer Center and four other hospitals, and approximately 6,000 faculty and resident physicians, I am pleased to submit comments to the proposed regulations by Agency for Healthcare Research and Quality (AHRQ) relating to implementation of the Patient Safety and Quality Improvement Act of 2005. As a strong proponent of patient safety and more specifically, the creation of a voluntary reporting system to promote patient safety (PSO), the University of Texas System welcomes the efforts of the AHRQ.

In developing these comments, The University of Texas System ("parent" organization) contemplated creating a PSO comprised of its six academic health centers ("component organization").

Ability of Healthcare System employees who work for: (a) the parent organization or (b) one of the system hospitals to participate in a PSO

The UT System believes AHRQ made the correct decision to allow the exception in proposed 42 CFR §3.102(c)(1)(ii) to the general requirement that a component PSO maintain patient safety work product separately from the rest of its parent organization(s).

The UT System is similar to many hospital systems in that it has a wealth of in-house patient safety expertise. For instance, M.D. Anderson has developed software for gathering and reporting patient safety data. Dr. Eric Thomas of the University of Texas Health Science Center Houston is on AHRQ's Editorial Board and coordinates one of the three Patient Safety Centers currently designated by AHRQ.

To utilize its existing patient safety expertise, the UT System desires to structure its PSO to organize a Patient Safety Committee with experienced representatives from each of its six healthcare facilities. This Patient Safety Committee may establish various ad-hoc committees to analyze data on certain issues and to recommend curative action. These ad-hoc committees would also usually be composed of in-house experts. Using in-house expertise would eliminate the need for costly outside medical directors and consultants, greatly reducing PSO expenditures. Lower expenditures increases the likelihood the UT System and other hospital systems would establish a PSO.

Furthermore, the patient safety recommendations of in-house experts are more likely to improve patient safety, in our opinion, because outside consultants are unfamiliar with the

cultural context and circumstances of each of our healthcare facilities. Such review and recommendation would also be more readily accepted since it results from in-house experts.

As to the proposed standard, in 42 CFR §3.102(c)(1)(ii), we believe more clarification is needed, especially for teaching hospital systems.

As currently proposed, every physician whose work is solely the provision of patient care may contract with a PSO to review identifiable patient safety work product. If a clinician's duties are not solely patient care, the test is whether the clinician's work could be influenced by knowledge of identifiable patient safety work product.

In a teaching hospital, every physician who supervises a resident or intern has work which is not solely the provision of clinical care because such physician's duties include the evaluation of the job performance of those residents and interns. In those situations, if a physician supervising a resident were to review a patient safety report on a resident's care, that report with identifiable patient safety work product might influence the physician's recommendations concerning the resident's future career.

So, the test under the proposed standard would prohibit the vast majority of physicians in a teaching hospital system from adding their expertise to a PSO, thus requiring a PSO to utilize outside consultants which would greatly increase a PSO's expenditures.

The UT System recommends that the proposed 42 CFR § 3.102 (c)(1)(ii) be clarified so that ONLY those employees of a hospital system (either of the parent entity or an individual hospital) who serve on hiring, credentialing, or peer review committees be prohibited from executing a contract with the PSO to review and evaluate identifiable patient safety work product.

Exclusion of Self-Insured Organizations

Subpart B § 3.102(a)(2) restricts health insurance issuers or components of health insurance issuers from seeking status as a PSO. While it may be reasonable to do so, the current regulations do not address the provision of a health insurance plan (primarily to its own employees) through an affiliated but separate nonprofit entity. If the hospital were a component entity of a PSO, does the offer of a health insurance plan by the nonprofit entity affiliated with the hospital disqualify the hospital from membership in a PSO? Is the intent of the rules such that no entity offering a health insurance may even participate in a PSO? We believe that clarification of this rule is necessary so that entities do not invest resources in attempting to become certified as a PSO only to learn that such an insurance plan would disqualify the PSO.

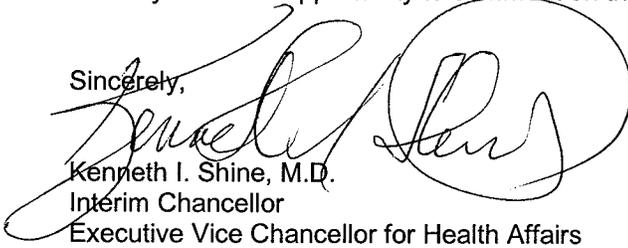
Separate Information System and Staff

Several aspects of the proposed rule address the separateness of the organization, data systems and staff. Subpart B § 3.102(c) identifies additional requirements for certification beyond the 15 general requirements. For instance, under Subpart B §3.102(b)(2)(i) the PSO must certify that its mission and primary activity is to conduct activities to improve patient safety. We are hopeful that this requirement does not require the parent organization's primary mission to be patient safety. Further, § 3.102(c)(1)(B) requires that the PSO "not have a shared information system that could permit access to its patient safety work product". The comments state that a component PSO may not store patient safety work product in information systems or databases to which others have access. 73 Fed. Reg. 8130. Section 3.106(b)(2) of the proposed rules identify the security framework for data systems. While we applaud the efforts to preserve

confidentiality with only limited access, sharing of computers and is often necessary for efficient operations, particularly in academic centers. Based on our own experience with such systems, confidentiality can be maintained without the necessity of completely separate computers. Reference is also made to the necessity of separate staff for the PSO (see 73 Fed. Reg. 8119). The most significant costs in development of any organization, including a PSO, are those associated with data systems and staff. To require complete separateness of data systems and staff will deter the development of a PSO, thus thwarting the opportunity to enhance patient safety. Clarification regarding the degree of separateness required is imperative.

Thank you for the opportunity to comment on the proposed rules.

Sincerely,



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Interim Chancellor
Executive Vice Chancellor for Health Affairs

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