Memorandum

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FROM: PSO Work Group

DATE: September 6, 2013

SUBJECT: Implementing a PSO within an ACO

Recently, representatives from AHRQ agreed to engage in periodic "listening sessions" with the PSO Work Group ("Work Group") which was established by the Medical Staff Credentialing and Peer Review Practice Group of the AHLA. The Work Group is made up of a cross-section of health care attorneys across the country with varying degrees of corporate, regulatory, litigation and other experience including the creation of and participation in ACOs and PSOs.

The first AHRQ/PSO Work Group listening session occurred on July 22, 2013, during which two topics were scheduled for discussion. The first issue addressed was to what extent, if any, can patient incident reports be treated as patient safety work product.

The second topic was a question AHRQ posed to the Work Group regarding our thoughts and analysis on how an accountable care organization ("ACO") can implement a PSO within its clinically integrated network given the different corporate, joint venture and contractual arrangements by and between the participating providers. Due to time constraints, we were not able to address this question in sufficient detail. To help facilitate this discussion, the Work Group offered to prepare an overview and summary analysis for submission to AHRQ in advance of a to-be-scheduled conference call. It should be noted that the ACO Credentialing Work Group of the MSCPR also was separately tasked with this question.

The comments and summary analysis in this memo is the product of a combined effort by both Work Groups but should not be considered a formal legal opinion by any of the individual members, the Work Groups, the MSCPR or the AHLA.

I. Overview

An ACOs is a term used to generally describe a clinically and financially integrated network of participating licensed providers. ACOs include those that have applied to and have been approved by CMS for participation in the Medicare Shared Savings Program pursuant to the ACO Final Rule as promulgated under the Affordable Care Act ("ACA"), of which there are approximately 250 around the country. In addition, there are many other integrated networks that simply describe their structure as an ACO but which have not formally sought ACO certification for Program participation.

Although one of the principal goals of an ACO is to create an organizational structure that is able to coordinate patient care services over a continuum of care so as to maximize quality and reduce health care costs, the manner in which these ACOs are organized and operate varies greatly. There is no common legal standard or required form that ACOs must take. In fact, the ACO Final Rule purposefully was designed to promote flexibility and innovation in order to encourage providers to address the challenging health care needs of diverse patient populations in rural, suburban and urban markets. Not surprisingly, therefore, the CMS-certified ACOs include health systems comprised of hospitals, employed practitioners and controlled affiliates, joint venture and co-management arrangements, independent contractors, IPAs and PHOs. Some ACOs also include a separately controlled health plan.

II. Relevant Questions Regarding ACO Participation in and Implementation of a PSO

In order to determine whether and how an ACO and its participating providers can take advantage of the confidentiality and privilege protections and other benefits available under the Patient Safety Act ("PSA"), there are some initial questions that need to be addressed.

A. Is the ACO a "provider" under the PSA?

Under the PSA, providers are eligible to contract with an independent PSO or create a Component PSO. The term "provider" is defined as:

> An individual or entity licensed or otherwise authorized under state law to provide health care services…

The definition goes on to set forth a non-inclusive list of provider facilities and practitioners such as hospitals, nursing facility, home health agency, and physician or health care practitioner's office/practice group. It is not clear how the term "otherwise authorized under state law to provide health care services" is to be interpreted. Whether on unlicensed entity will still be considered a "provider" under the PSA will require a review of the applicable state law. The Preamble states:

> "The statute provides confidentiality and privilege protections for reporting by individuals that actually provide health care services…The application of the term 'provider' in this rule is intended to give the full range of health care providers the ability to report information to, and work with, PSOs and receive confidentiality and privilege protections as set forth under the Patient Safety Act and this rule. Although we appreciate the administrative benefits of uniformity, and have tried to maximize the consistency or interoperability of this rule with the HIPAA Privacy and Security Rules, it would not be appropriate in this rule to adhere to any less inclusive definition of provider used in other regulations."

Therefore, if the ACO is a provider under the PSA it can contract with a component or a separate free standing PSO. Because the primary purpose of a PSO is to "conduct activities that are to improve patient safety and the quality of health care delivery", an ACO would not likely qualify as a PSO.

B. If the ACO is not a provider, does it qualify as a "parent" organization of affiliated providers or a component organization?

The fact that an ACO is not a provider under the PSA does not mean it cannot contract with a PSO and therefore access the protections and benefits of the PSA. A "parent organization" means an organization that:

> Owns a controlling interest or a majority interest in a component organization; has the authority to control or manage agenda setting, project management, or day-to-day operations; or authority to review and override decisions of a component organization. The component organization may be a provider.

"Component organization" is defined as an entity that:

1. Is a unit or division of a legal entity (including a corporation, partnership, or a Federal, State, local or Tribal agency or organization; or

2. Is owned, managed, or controlled by one or more separate parent organizations.

"Affiliated provider" means:

> With respect to a provider, a legally separate provider that is the parent organization of the provider, is under common ownership, management or control with the provider, or is owned, managed, or controlled by the provider.

Based on these definitions along with the Preamble discussions, a non-provider ACO which is a "parent" organization of one or more providers or component organizations, as that term is defined, can be part of a system-wide patient safety evaluation system.

But what if the ACO does not own a controlling management or ownership interest? The question then becomes whether it meets either of the two other prongs of the definition of a "parent organization" – does it have the authority to control or manage agenda setting, project management, or day-to-day operations; or the authority to review and override decisions of a component organization?

A CMS certified ACO is obligated to comply with various requirements relating to its legal structure, shared governance and management which include the following"

1. Must be a legal structure recognized under state law with sufficient authority to conduct business and to implement and enforce all ACO functions through a governing body such as:

    a. Adoption, implementation and enforcement of internal performance standards for quality of care services and utilization standards.

    b. Must be able to hold all ACO participants accountable for meeting all standards.

c. Must have a data collection and evaluation infrastructure.

d. Must provide CMS with an example of on individualized care plan.

e. Must develop and enforce a compliance plan.

f. Must meet and enforce CMS specified patient centeredness criteria, such as the final 33 quality metrics, across the ACO care continuum and processes to report on quality and cost metrics.

2. ACO must be managed by an executive, officer, manager or general partner under the control of the governing body.

3. ACO's governing body must have a board of directors that has adequate legal, management and executive authority to implement and enforce all requirements under the ACA and Final Rule.

Based on these requirements under the ACA, a CMS certified ACO which meets these requirements, in our view, clearly would satisfy the management and control prong of the "parent organization" definition given its control over setting the agenda, managing projects and running the day-to-day operations of the ACO and participating providers at least with respect to ACO activities. Whether a non-CMS certified, non-provider ACO can qualify as a parent organization will depend on whether it can satisfy the definition of this term under the PSA based on the facts and circumstances of its operations.

But what if an ACO exerts the required ownership, control or management over ACO services but not all of the health care services offered by the participating providers? For example, assume that an independent nursing home and multi-specialty physicians group participate in an ACO via contract or joint venture but only are involved in the treatment of Medicare patients as part of the Shared Saving Program but do not participate in the ACO's plans or treatment of commercial or self-pay patients? The ACO, therefore, would not meet the definition of a parent organization under the PSA for these activities. The patient safety, reports, analyses, etc., relating to these non-ACO PSES, consequently could not be shared with the ACO and its owned, controlled and managed providers and component organizations as part of the ACO's PSES. If these providers wanted to seek the protections and benefits under the PSA for these non-ACO activities they would need to develop separate PSESs and contract with either the ACO's PSO or one or more other PSOs.

C. If an ACO is not a Provider, can its participants access its benefits and protections through a "Shared PSO" Model?

If an ACO cannot meet either the "provider" or the "parent organization" requirements for participation in a PSO, then we suggest, as an alternative, that its component/provider affiliated or contract members could access the benefits and protections of the PSQIA through an "ACO Sharing Group" under a "Shared PSO" model, as described below.

Under this model, each qualified provider, or provider group that participates in the ACO (e.g., physician practice, individual physicians, hospital and other provider entities) would individually

contract with a designated PSO. This PSO could be a component PSO of one of the ACO participants (e.g., of a hospital or its parent company), or it could be a completely independent, third-party PSO.

Each ACO member would individually contract with the designated PSO, and create its individual PSES, or arguably be part of a system-wide PSES for purposes of collecting and reporting data to the PSO. The ACO members would agree upon specific protocols, policies and procedures for the collection and reporting of data related to the ACO to the PSO.

Each ACO member would sign a Consent Agreement pursuant to 42 CFR § 3.206(b)(3) for the disclosure of its PSWP to the other ACO members in furtherance of the quality/safety objectives of the ACO, and thus create an "ACO Sharing Group." Section 206(b)(3) has three requirements for the Consent Agreement to be effective, as follows: (A) the Consent Agreement must be in writing and signed by the provider from whom authorization is sought; (B) it must contain sufficient detail to fairly inform the provider of the nature and scope of the disclosure being authorized; and (C) it must be retained by the disclosing entity for a period of six years from the date of the last disclosure made in reliance on the authorization, and available to the Secretary upon request. PSWP disclosed pursuant to the authorization of the identified providers retains its confidentiality protections and may not be further disclosed. 42 CFR § 3.208(a).

Through this mechanism, we suggest that the ACO members could create an "ACO Sharing Group" group that would facilitate the exchange of PSWP between and among the ACO members in furtherance of the quality/safety objectives of the ACO. For instance, based on the data collected and reported to the PSO by the ACO members, the PSO and the "ACO Sharing Group" could develop quality/safety protocols and best practices for implementation by the ACO members to improve quality throughout the ACO and in accordance with the ACO's quality objectives.

Importantly, each of the ACO members would be individually accountable for continued adherence to all required elements of PSO participation and of the Consent Agreement, including, in particular, maintaining the confidentiality of PSWP and ensuring that PSWP is used only as permitted by the Patient Safety Act regulations.

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