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January 9, 2019

Ms. Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-3367-NC
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

RE: CMS-3367-NC Request for Comment on Accreditation Organizations Conflicts of Interest

Dear Ms. Verma:

The Jayne Koskinas Ted Giovanis Foundation for Health and Policy (JKTGF) is pleased to submit comments to the Centers for Medicare and Medicaid Services (CMS) on the real and perceived Conflicts of Interest (COI) of Accrediting Organizations (AOs). As one leg of the three-legged stool of quality care, the AOs are the bedrock of good quality of care and any impactful relationships between and among the providers of care (the regulated) and the review organization (the AO) that could impact on the objectivity of the AOs must be avoided at all costs if we are to have confidence in the quality platform. Also important are relationships between AO activities. Relationships must either be non-existent or remain at strictly arms length to assure the objectivity of the review of quality policies, practices and services. This review, along with meaningful and accepted process and outcome quality measures and patient engagement will contribute to better care.

Our comments lie in several areas including: provision of consulting services to reviewed and non reviewed providers; actual and perceived COIs; and AO board of director (BOD) and provider involvement conflicts which are address in the following paragraphs.

I. AOs providing consulting services to providers they may or may not subsequently review for an accreditation (also, providers that are represented on the BOD or otherwise)

Many AOs have created consulting arms for AO type services. The development of these consulting arms was likely done to generate additional revenue streams for the AO. Such services may serve the purpose of a pre review for the provider or to identify system failures at the provider. For the AO the revenues from these services inherently take pressure off the fees charged by the AO to the providers that are reviewed and allow the AO to be more competitive from a price perspective.

The very existence of these consulting relationships in themselves creates real and/or perceived conflicts of interest. What happens when the AO accreditation staff are reviewing a provider that has procured consulting services from the consulting division of that AO? Could there be a tendency for the accreditation reviewers to give that provider a pass on something identified? What about the more subtle passes on cited items that occur merely because the accrediting reviewers know the provider has received such consulting services? What about the situation where the accreditation division finds something wrong with what the consulting arm did or should have found but did not? In such situations will the accreditation personal call out/report the consulting personnel and is that made public, even to CMS? Are such incidents documented and/or required to be reported simultaneously with its findings or at the next CMS contract review and approval?

Complicating or frustrating the identification of these situations and instances was the combining of the AO and state agency (SA) review processes. Such combination, while efficient from a provider perspective, may have been detrimental from a checks and balances perspective. Reviews are by their nature merely snapshots at a moment in time and such may or may not be an accurate reflection of the overall function of provider policies and processes. So the reviews might fail to adequately review or test the systems, policies, and practices that are in place, how they work and their effectiveness.

Conversely, is there an incentive for an accrediting AO function to level criticisms on a provider that has received consulting services from a competitor AO consulting arm? Complicated to say the least and virtually impossible to regulate or control. One way out is to require a blanket prohibition for any AO to have a consulting function. If proposed this likely will be counter lobbied by the AOs. But, retention of such services does not address the problem. It only ignores it. All of these situations indicate there should be strict requirements established in order to become an approved AO.

All of the above mentioned scenarios and more can and do occur. The question remains: what happens when they occur? Are we to have faith the AO will identify these errors and it will do the “right” thing and criticize its own sister division? What systems, policies and practices are in place to identify and remedy such failures?

II. Accrediting Organization Board of Directors and Provider Leadership Conflicts of Interest

Another COI issue area related to AOs, is provider representation on the AO board of directors (BOD). While input from the provider community is important to the AOs such representation on the BOD can at a minimum pose complications and problems at worst. Representation on the AO BOD poses risks for the AO's objectivity for the industry generally and to that particular provider specifically.

Payment for BOD member services also poses risk. On the one hand such payments might assure engagement from the BOD members in that they will actually be engaged in the AO BOD oversight role. However, on the other hand it solidifies the interlocking effects for the specific providers involved and to the industry more generally. This is a very important aspect of objectivity. As an example, our Foundation has an explicit policy of not dealing contractually with the firm of any member of our BOD. In the event such was to be considered a predicate step would be that the applicable BOD member would be required to resign from the Board before even being considered for a contractual relationship. Even then, such relationships are frowned upon. This is an example that such policies can be and are in place. Granted this type of limitation might allegedly preclude access to quality services of the BOD member firms; however, the market place is robust enough to allow an adequate selection.

III. Actual and Implied and Real And Perceived Conflicts

Actual and Implied Conflicts

Key to assuring quality are the processes that are in place at the provider that can identify and remedy issues before they become problems. Beyond the direct relationships developed by having providers sitting on the AO BOD (discussed elsewhere) is the implied nature of influence. Relationships evolve and build over time. Individuals that possess such relationships will have a tendency to talk to one another and the nature of those conversations generally are not public or recorded. So, such conversations are not in any disclosed or public domain. While not inherently nefarious, they can influence behavior. This creates the environment whereby the AO staff can communicate areas of interest or specific faults observed at that provider and the provider can rehabilitate those issues before a report is issued. However, the public will never know that deficiencies were present for the period, perhaps a year or more, that preceded the review date. Such information suggests that the provider's inertia allowed it to lapse into a deficient state but that it corrected such deficiency once alerted. Therefore, no one knows what was wrong or that the providers systems failed to identify the deficiency. Fundamentally, it is the providers internal systems that must be effective enough to identify and remedy any deficiencies and the public relies on the provider identifying, addressing and solving the identified issue to prevent harm.

Beyond direct BOD AO staff interaction that is of an explicitly instructional nature is the implied nature of influence on the objectivity of the reviewer. Because the reviewers know that the provider they are reviewing is represented on the BOD of

the AO or have relationships, which allow conversations, they may, and often do, tend to tread lightly in their reviews and resultant comments on what was reviewed. The non-public nature of these phenomena can and should be troubling to beneficiaries. However, we doubt the beneficiaries are even aware that such exist. These same phenomena often occur between regulated providers or their associations and the agencies that regulate such providers, such as the CMS. This type of influence is referred to as regulatory capture.

Clear and required separation between the regulator and the regulated is a good thing (when coupled with competent and knowledgeable regulatory staff) and such is critical between the AO and the reviewed providers.

Real and Perceived Conflicts
Having members of the regulated community on the AO review entities BOD may provide the AO with information about the reviewed provider types. Such insights are valuable in developing review parameters and areas of scope. However, such representation very seldom creates any positive perception on the part of the public. The only thing that prevents this is ignorance on the part of the public, which is never a good thing but undeniably exists. CMS should take actions to increase public awareness of the issues surrounding these conflicts.

Recommendations to Create Objectivity and Assure Independence of AO in Review Activities

Our recommendations follow and are aligned with the subject areas discussed above.

1. Assuring that the AO provision of consulting service does not have a negative effect. (Recommendations relating to Section I above.)

A. Prohibit all approved AOs from the provision of consulting services of any type related to the subject matters of quality reviews.
This represents the best option. However, if this option is not selected, several of the other options below could work in tandem.

B. Require that any approved AO not offer consulting services to providers it reviews and if the AO inadvertently finds such services were performed, the AO should resign from that provider's review.

C. Stipulate that any AO that is CMS approved is explicitly prohibited from performing any AO review of a provider entity represented on that AO's BOD.
There should be specific prohibitions for all AOs in that the AO cannot review any entity represented on the AO BOD. This will achieve some separation and assure the objectivity of the review of that particular provider.

D. In the AO application to CMS for deemed status require that the AO provide their review results when they have reviewed a provider that utilized their own AO consulting division as well as the review of other AO consulting division no less often than quarterly.

E. CMS should calculate a "disparity rate(s)" of items cited and items missed by consultants and require such be reported publicly.
Based on information from the external review (suggested in III. A below) of any deemed AO the CMS should require the calculation of a "disparity rate." Such disparity rate should be calculated using data from the most current AO/SA review and the internal consulting review results if such provider has had an internal consulting review by any AO consulting entity.

F. At least require that the AO establish a Chinese Wall between its review and consulting arms including appropriate policies and procedures that CMS could review.

2. Improving the Credibility of AO Leadership and Garnering of Input
(These recommendations relating to II Section above.)

A. AOs should use Advisory Councils (AC) in Lieu of BOD memberships.
The AO can gain provider input by using ACs rather than having provider representatives on its BOD. By definition this includes some separation between the AO and the providers being reviewed. AC members should be rotated periodically such as every 2-5 years or a continual rotating basis varied by project/subject with which they are involved. This also contributes greatly to counter the public and regulatory agency perception of the ability to collude in any review.

B. Require beneficiary representation on the AO BOD and require that such representation be current Medicare beneficiaries and such representatives must not be from an organization that merely represents beneficiaries since these entities tend to have self-interests rather than the interests of the individual beneficiaries.
Obtain input directly from beneficiaries. Once appointed any such beneficiaries will learn the industrial COI issues, policies and practices over a 2-4 year appointment time frame. There could be a prescribed minimum portion of beneficiary representatives on the AO BOD e.g. 30.0%.

3. Addressing Actual and Implied and Real And Perceived Conflicts
(Recommendations relating to in Section III above.)

A. Require an external review of the AO's COI policies and practices as well as any interactions with the AO's BOD related entities.
Require all AOs to have an annual external objective review of their COI policies and practices and also of the AO's involvement with any AO BOD member provider. Such reviews should include specific review of the COI policies and practices, any lapses in such policies and practices, and where the identification of such lapses led to

recommendations and enhancements to those policies and practices. All such reviews and reports should be required to be made public on the AOs website and be clearly labeled as such. A public accounting firm could perform such external objective reviews; however, the accounting firm that performs that AO's external audit must not perform these reviews.

B. Require the public reporting or reporting to CMS of any and all errors found by any AO consulting division either for their own reviewed providers or others and make those errors or findings public both on the AO's and provider's website.
Transparency is a critical part of any oversight of the AOs. Therefore, required sunshine on their activities is important.

C. Require consulting AO divisions to report when they believe that other AO consulting divisions are predatorily finding errors in their reviews.
Transparency is a critical part of any oversight of the AOs. Therefore, required sunshine on their activities is important.

D. Inform Medicare beneficiaries of these issues and their importance and impact on quality.
The fact that the CMS will make strict COI requirements will be a sign of the importance the agency places on systems and processes for the identification and remedy of safety related matters as well as the separation of the regulated from the AO reviewers. Once adopted such polices should be followed by PSAs (public service announcements) targeted on beneficiaries to alert them to the issues and to be aware of and report any inappropriateness to the CMS. Related information should be placed and highlighted in the packets provided to beneficiaries by CMS included in a section in the "Medicare & You" handbook and potentially in material handed to the beneficiary by the providers themselves.

Conclusion

The JKTGF appreciates the opportunity to provide comments on the AO COI issues and to offer solutions on issues involving interactions between and among the AOs and the providers that are reviewed. If you have any questions regarding these comments, we would welcome the opportunity to engage in a discussion of the substantive points and recommendations above.

Sincerely,

Theodore Giovanis