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CMS Issues Final ACO Rules: Key Legal Implications for Hospital & Health System ACOs

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On June 4, 2015, the Centers for Medicare & Medicaid Services (CMS) released a final rule (Final Rule) containing changes to its Medicare Shared Savings Program (MSSP). Some of the changes codify informal guidance that the agency had previously issued, while others represent material changes for the MSSP. The Final Rule, as well as commentary issued with the rule, has important implications for accountable care organizations (ACOs), particularly those owned and operated by hospitals and health systems.

In many respects, the primary focus of the Final Rule is to make changes designed to ensure continued robust participation in the MSSP. Under the previous rule, an ACO was permitted to participate in Track 1 (with shared savings potential, but no risk for losses) for only the initial three-year agreement period. After the initial three-year period, ACOs were required to move to Track 2 (which includes down-side risk for losses). Without the changes adopted in the Final Rule, CMS estimated that fewer than 15 percent of ACOs would opt for continued participation under downside risk in Track 2. Under the Final Rule, ACOs can renew in Track 1. At the same time, CMS has made changes to Track 2, and created a new Track 3, to incentivize ACOs to move to a two-sided performance-based track. Under Track 2, ACOs will now have a choice among several options for their applicable minimum savings rate and minimum loss rate, allowing ACOs to more closely tailor Track 2 to their individual risk tolerance. In addition, the Final Rule creates a Track 3, which incorporates a higher shared percentage (75 percent), prospective assignment of Medicare beneficiaries, and the opportunity for a programmatic waiver of the three-day skilled nursing facility (SNF) rule (which permits payment for otherwise covered SNF services when a beneficiary is admitted to a SNF without a prior 3-day inpatient stay).

Those are very important changes that are adopted in the Final Rule. However, in this document, we focus on some other changes incorporated into the Final Rule that are relevant for legal compliance, especially for ACOs sponsored by hospitals and health systems. The following checklist summarizes several of these legal items for ACOs to consider:

ACO Legal To Do Checklist

?	If ACO has a parent company with res legal structure in light of CMS final rul governing body and the Internal Reve the importance of control by tax-exem (or joint-ventured) ACOs
?	Review composition of ACO governin CMS expectation on the complement representatives on the governing bod
?	Determine whether legal entity that is activities and, if so, confirm complianc requirements
?	Confirm that Medicare beneficiary ser is not also an ACO participant
?	Review template ACO participation ag required elements in final rule and to contracting parties
?	Initiate process to understand legal st participant group practices to identify the tax identification number of that gr practice name or location

Hospital Parent Reserved Powers

New subsection 42 C.F.R. §425.106(a)(2)(i) provides that the governing body of the ACO must: (i) be the same as the governing body of the legal entity that is the ACO; (ii) be separate and unique to the ACO and not the same as the governing body of any ACO participant; and (iii) satisfy all other requirements of the rule, including the fiduciary duty requirement. In commentary to the final rule, CMS explains that these additions are designed to preclude both delegation of all ACO decision-making authority to a committee of the governing body and retention of ACO decision-making authority by a parent entity.

CMS further states in commentary to the final rule that while it recognizes that a parent organization may wish to retain certain authority to protect the parent company and ensure the subsidiary's success, the ACO governing body must retain the ultimate authority to execute the functions of an ACO. These include: (i) processes specified in 42 C.F.R. §425.112 to promote evidence-based medicine and patient engagement, report on quality and cost measures and coordinate care; and (ii) holding leadership and management responsible for the ACO's activities. Significantly, CMS states in the commentary that they believe the authority of the ACO board extends to appointment and removal of the individuals serving on the governing body, leadership and management, and determining how shared savings are used and distributed among ACO participants and ACO providers/suppliers.

Health systems that wholly own and control ACOs/clinically integrated networks (ACO/CINs) as separate entities typically reserve ultimate authority over these matters to the parent of the ACO/CIN rather than the ACO/CIN board. According to the commentary to the final rule, such a governance structure would not meet the requirements for MSSP participation. Therefore, health systems will need to carefully consider the implications of CMS' governance requirements for their participation in the MSSP and other legal, regulatory and operational implications of the ACO/CIN parent entity not having powers traditionally reserved to parent entities such as the right to appoint and remove ACO/CIN board members and approve the design of incentives and associated distributions from

innovative payment programs. For example, the ACO/CIN's legal structure and relationship to the parent entity should be evaluated for consistency with state corporate law. Health system parents of multiple entities operating different service lines that retain ultimate authority over such matters should consider the potential system-wide governance implications of deviating from standard system reserved powers.

Governing Body Composition

CMS has included in 42 C.F.R. §425.106(c)(1) the statutory requirement that an ACO have a mechanism for shared governance among ACO participants. CMS explains that by way of example, an ACO comprised of more than one ACO participant should not include representatives from only one ACO participant. CMS further states that ACOs with extensive ACO participant lists should have representatives from many different ACO participants on the governing body.

CMS has also added a requirement in 42 C.F.R. §425.106(c)(2) that the Medicare beneficiary representative on the ACO governing body not be an ACO participant.

ACOs should review their board composition to ensure compliance with these requirements.

Participation Agreement Requirements

The Final Rule adds a new section (42 C.F.R. § 425.116) that sets forth requirements for agreements between an ACO and an ACO participant or ACO provider/supplier. Among other requirements, the Final Rule (42 C.F.R. § 425.116(a)(1)) requires the ACO to contract directly with each ACO participant (e.g., medical group) or ACO provider/supplier, rather than through an existing IPA or PHO that was formed for other purposes. In commentary, CMS states that typical IPA contracts are inappropriate and unnecessary for purposes of MSSP participation. CMS further states that an ACO and ACO participant may use a contract unrelated to the MSSP as an ACO participant agreement only when it is between the two parties and is amended to satisfy the requirements for ACO participant agreements under the MSSP. Most of the other regulatory requirements are consistent with sub-regulatory guidance previously issued by CMS.

An ACO must ensure that all providers/suppliers billing through an ACO participant comply with MSSP rules. It can fulfill this obligation by contracting directly with such providers/suppliers, in which case it must do so in compliance with new requirements set forth in the Final Rule. Alternatively, it can do so by requiring contracting ACO participants to ensure that all providers/suppliers comply with the MSSP rules. In any event, obtaining some form of "joinder" commitment from provider/suppliers is a best practice in this area.

In adopting these new provisions, CMS acknowledged that because of the "timing of" the Final Rule, "ACOs may struggle to incorporate these requirements in time to submit 2016 applications or request for renewal." As a result this portion of the Final Rule does not apply to 2017. Nonetheless, counsel to ACOs should review their existing template participation agreements to ensure that they are consistent with these requirements, which will apply in 2017.

Acquisitions of ACO Participants

Mergers and acquisitions of health care providers can present significant issues with respect to the methodology for beneficiary assignment to ACOs. In particular, the question is when a Medicare enrolled provider (*e.g.,* a group practice) is acquired by, or merged into, another Medicare-enrolled

provider that is an ACO participant, to what extent is the Medicare claims history of the acquired group considered for purposes of beneficiary attribution and establishing savings benchmarks. The Final Rule codifies current operational guidance, with some minor revisions, at 42 C.F.R. § 425.204(g). In particular, the Final Rule provides that an ACO may include an acquired Medicare-enrolled tax identification number (TIN) on its participant list if the acquired Medicare-enrolled TIN was subsumed in its entirety by an ACO participant and no longer participates in Medicare. It is worth noting that even if an ACO does not submit to CMS the TIN of the acquired Medicare-enrolled entity, all the provider/suppliers associated with that entity will necessarily become provider/suppliers associated with the ACO if the acquiring entity remains an ACO member.

These rules can have material impacts on the provider/suppliers that are part of, and the beneficiaries assigned to, an ACO. This is especially the case where an acquired entity may operate in a different geographic region. Hospitals and health systems that sponsor an ACO and are engaged in physician practice acquisition activities should add these ACO impacts to their standard pre-transaction due diligence.

Choice of Legal Entity for ACO and Fiduciary Duties

The Final Rule makes it clear that existing legal entities (as opposed to legal entities created specifically to enroll as MSSP ACOs) can serve as ACOs only in limited circumstances. Specifically, the Final Rule amends 42 C.F.R. 425.106(b)(3) to clarify that the fiduciary duty owned by a governing body member to the ACO includes the duty of loyalty. Consistent with prior sub-regulatory guidance, CMS interprets this provision in the Preamble to mean that an entity engaged in other activities [such as an independent practice association (IPA)] may serve as an ACO only if all members of the entity (in this example, the IPA) participate in all lines of business. This effectively precluded the use of an IPA or physician-hospital organization (PHO) structure as the ACO where the IPA or PHO allows providers to opt out of network contracts, including the MSSP contract. As CMS states: “[W]e believe it would be difficult for the members of the IPA’s governing body to make decisions in the best interests of the ACO if only some of the group practices that compose the IPA are ACO participants.” It would appear that this interpretation is based on the fact that the regulation requires the existence of a fiduciary duty “to the ACO,” which is distinguished from a fiduciary duty to the legal entity operating the ACO. Typically fiduciary duties are owed to legal persons (*e.g.,* legal entities and natural individuals), not to activities, so this requirement has historically been the subject of some debate.

The Final Rule also clarifies that an ACO formed by a single ACO participant may use its existing legal entity and governing body, provided that it satisfies the other requirements in subsections 425.104 and 425.106 of the MSSP rule.

The take away from these changes is that a legal entity that serves as an ACO can engage in non-ACO related activities only if: (a) all physicians who participate in that legal entity participate in all lines of business (*i.e.,* participate in all ACO and non-ACO activities); or (b) the ACO is constituted from a single legal entity. Any ACO that conducts non-ACO activities would be well advised to review its legal structure to ensure compliance with these recently clarified requirements.

Compliance Date

Under 42 C.F.R. §425.212(a)(1), an ACO is subject to all regulatory changes that become effective during the MSSP agreement period, with the exception of eligibility requirements concerning the structure and governance of ACOs. Therefore, the changes above with respect to ACO structure and

governance appear to be not applicable until an ACO renews its three-year agreement with CMS. However, ACO should be cautioned that in many cases CMS takes the position that changes in the Final Rule simply clarify pre-existing law. As a result, ACO should not delay in evaluating their compliance with the standards of the Final Rule. If such an evaluation suggests there are areas of actual or potential non-compliance the ACO can establish a corrective action plan that takes into account the delayed compliance date for certain provisions.

Conclusion

The Final Rule includes other changes not described in this document. It is a rule with far-reaching impacts. ACOs and organizations considering applying to become ACOs should make sure they understand the compliance, operational and financial impact of the new rule.

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