The New York State Department of Health Releases Long-Awaited Proposed Regulations Authorizing the Formation of ACOs

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October 2014

The long-awaited proposed regulations authorizing the formation of accountable care organizations ("ACOs") in New York are finally here.[1] Interested parties may comment on the proposal until December 1, 2014.[2] The regulations will also impact entities applying for Delivery System Reform Incentive Payment ("DSRIP") Program funds, as the DSRIP application was recently amended to allow DSRIP Performing Provider Systems ("PPSs") to also apply to become an ACO as part of the DSRIP application.[3] Another notable provision of the proposed regulations is that an independent practice association ("IPA") may become an ACO.[4]

The main purpose of the ACO model is, of course, to allow the participants to share in any "shared savings,"[5] as defined by the regulations, with immunity from various regulatory limitations. Certified ACOs will also be eligible for the waiver of certain regulatory requirements that are available under the DSRIP Program without having to separately apply for the waiver. ACO shared savings can be either under the "one-sided" model, which allows an ACO to share in any savings with the third-party payer but not be liable for any losses,[6] or the "two-sided" model, under which an ACO is eligible for shared savings and also liable for any losses.[7]

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[1] The full text of the proposed rule is available here: http://w3.health.state.ny.us/dbspace/propregs.nsf/4ac955878100677485256 9bd00512fda/988f8b596c6fef9a85257d71004ea1d7?OpenDocument (last visited Oct. 17, 2014).
[2] The preamble to the proposed rule is available here: http://w3.health.state.ny.us/dbspace/propregs.nsf/4ac955878100677485256 9bd00512fda/988f8b596c6fef9a85257d71004ea1d7?OpenDocument.
[3] The DSRIP PPS Organizational Application is available here: https://www.health.ny.gov/health_care/medicaid/redesign/dsrip_project_plan_application_draft.htm (last visited Oct. 17, 2014).
[4] 10 N.Y.C.R.R. § 1003.6(g).
[5] "Shared savings" is defined as the "portion of savings generated by an ACO when its expenditures for health care services to its population are below projected benchmark expenditures, with no downside risk to the ACO for losses." 10 N.Y.C.R.R. § 1003.2(v).
[6] 10 N.Y.C.R.R. § 1003.2(o).
[7] 10 N.Y.C.R.R. § 1003.2(y).

The proposed regulations define an ACO as "an organization of clinically integrated health care providers [that are] accountable for the quality, cost, and delivery of health care to a defined population."[8] The Commissioner of the New York State Department of Health will issue Certificates of Authority ("COA") to entities that satisfy the regulatory criteria for ACOs. Among the ACO criteria are the existence of stated mechanisms for governance, accountability, and the distribution of funds.[9] An ACO must have a plan for coordination of care to assure that all medically necessary health care services are available to and used by the patient, including evidence-based treatment initiatives and strategies for patient engagement. The regulations specify standards for the ACO's quality management improvement program, including a process for peer review.

Under the proposed regulations, IPAs, physician groups, health homes, Medicare-only ACOs, and hospitals are all eligible to become ACOs in New York.[10] An IPA may also qualify as an "administrative services organization" that provides "ancillary services" to the ACO, such as care management and technical support.[11]

To qualify as an ACO, the applicant must establish its ability to "provide, manage and coordinate health care for a defined population," and demonstrate how its "clinically integrated health care providers and administrative support organizations" will be "accountable for the quality, cost and delivery of health care to the individuals it serves."[12] To achieve ACO certification, a prospective ACO must also have a leadership and management structure that is reasonably and equitably representative of the ACO participants (at least 75 percent) and its patients. The proposed ACO must be organized as a "business corporation, not-for-profit corporation, limited liability company or partnership" in New York.[13]

Certification as an ACO offers numerous benefits for an entity. The ACO will not be in violation of state antitrust laws, provided that it qualifies for the "safety zone" established by the Federal Trade Commission.[14] Additionally, an ACO can request state action immunity as part of its ACO application, pursuant to criteria set forth in the proposed regulations, and will not be in violation of State laws related to fee splitting or limitation of referrals should immunity be granted.[15]

In addition to setting the framework for expanded use of the ACO model in New York, the proposed regulations provide insight for organizations evaluating which entity type will be most appropriate for its DSRIP application. The proposed regulations also authorize IPAs to become ACOs and allow IPAs to exercise the "powers and purposes"

[8] N.Y. Pub. Health Law § 2999-o(1) (McKinney 2012).
[9] N.Y. Pub. Health Law § 2999-p(1) (McKinney 2012).
[10] 10 N.Y.C.R.R. § 1003.6(d)(1). While ACOs do not have the authority to operate a hospital or provide hospital services, that restriction does not apply "to the extent the corporation or company has already received certification or licensure," thereby allowing a currently operating hospital to also receive certification as an ACO.
[11] 10 N.Y.C.R.R. § 1003.2(c).
[12] 10 N.Y.C.R.R. § 1003.3.
[13] 10 N.Y.C.R.R. § 1003.1(a)(1).
[14] 10 N.Y.C.R.R. § 1003.14(a)(1).
[15] 10 N.Y.C.R.R. §§ 1003.14(a)-(c).

that are allowed under an approved DSRIP Program project.[16] How the ACO and DSRIP applications will be coordinated and reviewed remains to be seen. For example, if a PPS applicant does not receive approval to function as a PPS under DSRIP but requested ACO certification in the DSRIP application, will the Department of Health grant the ACO certification absent DSRIP participation? Choosing an entity type for an ACO, particularly if done in conjunction with the development of a DSRIP project plan, will become an even more complex process of matching the regulatory waivers potentially available under each organizational model to the organization's own short- and long-term strategic needs.

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[16] 10 N.Y.C.R.R. §§ 98-1.2(w), 98-1.5(f)-(g).