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#### **CMS RELEASES REQUEST FOR APPLICATIONS FOR ACOS TO PARTICIPATE IN NEW ACO MODEL**

The Centers for Medicare & Medicaid Services (CMS), Center for Medicare and Medicaid Innovation, recently released a [Request for Applications](#) seeking accountable care organizations (ACOs) willing to engage in a higher risk, higher reward arrangement (Next Generation Model) than is currently available to ACOs participating in other CMS initiatives. The goal of the Next Generation Model is to test whether strong financial incentives for ACOs can improve health outcomes and reduce expenditures for Medicare fee-for-service (FFS) beneficiaries. An ACO participating in the Next Generation Model (Next Generation ACO) may establish relationships with the ACO's providers/suppliers, "Preferred Providers," and "ACO Affiliates" to provide services to beneficiaries aligned with the ACO. For the purposes of the Next Generation Model, a Next Generation ACO's Preferred Providers are Medicare providers and suppliers other than the ACO's providers/suppliers that contribute to the ACO's goals by extending and facilitating "valuable care relationships" beyond the ACO. Preferred Providers will not affect beneficiary alignment to a Next Generation ACO and will not be involved in quality reporting to CMS. ACO Affiliates are Medicare providers and suppliers other than the ACO's providers/suppliers that play a role in advancing the Next Generation ACO's cost and quality goals. ACO Affiliates include "SNF ACO Affiliates" and "Capitation ACO Affiliates," each discussed below. Preferred Providers may be ACO Affiliates.

#### **Next Generation Model Participation Requirements**

Many of the requirements for participating Next Generation Model ACOs mirror those of a traditional ACO participating in the Medicare Shared Savings Program (MSSP):

- The eligible providers and suppliers are the same.
- The legal entity requirements are the same. (Any ACO that participated in the MSSP or ACO Pioneer Model will be deemed to have met this requirement for participation in the Next Generation Model.)
- The responsibility and structure of the governing body are the same.
- The composition of the governing body of the ACO is the same except that (1) the Medicare

beneficiary serving on the governing body may not be a provider/supplier of the ACO and (2) the governing body must include at least one consumer advocate (with training or professional experience in advocating for the right of consumers), who may be the Medicare beneficiary.<sup>1</sup>

- Both have the same conflict of interest policy requirements.
- Both have the same leadership and management requirements.

## **Next Generation ACO Program Model**

### Financial Elements

The Next Generation Model tests an ACO's capacity to take on almost full financial risk in combination with a stable, predictable financial benchmark and payment mechanisms that promote investment in care improvement infrastructure.

#### I. Benchmarking

Unlike other ACO models, CMS will set a prospective benchmark for a Next Generation ACO prior to the start of a performance year, using expenditure, quality, and risk score data for Medicare Parts A and B for aligned beneficiaries. CMS will set the benchmark through four steps:

1. Determine the ACO's historic baseline expenditures using the ACO's historic spending for a single baseline year. The same baseline year will be used to set the benchmark for all three of the ACO's performance years in the Next Generation Model, with updates based on changes to the ACO's provider/supplier list.
2. Apply a regional projected trend in costs.
3. Adjust for risk based on the CMS Hierarchical Condition Category risk scores for the baseline year and the performance year populations.
4. Apply a discount that reflects (a) quality (a discount ranging from 2 to 3 percent), (b) the ACO's baseline expenditures compared to regional fee-for-service expenditures (a discount ranging from -1 to 1 percent) and (c) regional fee-for-service expenditures compared to national fee-for-services expenditures (a discount ranging from -0.5 percent to 0.5 percent). The Next Generation Model will not use a minimum savings rate.

CMS may revise the benchmarking methodology for the second and third program years.

#### II. Risk Arrangement

Next Generation ACOs will elect to participate in one of two risk models. They will share a higher percentage of any shared savings; beneficiary expenditures will be capped at the 99th percentile, and aggregate savings or losses will be capped at 15 percent of the Next Generation ACO's benchmark.

For Arrangement A, a Next Generation ACO and CMS share risk for Medicare Parts A and B:

- 80 percent sharing rate (program years 1–3)
- 85 percent sharing rate (program years 4–5)

For Arrangement B, a Next Generation ACO assumes 100 percent risk for Medicare Parts A and B (subject to the 15 percent cap on aggregate savings or losses).

#### III. Payment Arrangements

The Next Generation Model will test whether alternative payment arrangements, combined with normal fee-for-service payments, are effective in encouraging the Next Generation ACO to invest in infrastructure and care coordination activities to improve health outcomes for aligned beneficiaries. Next Generation ACOs will select one of the four following payment arrangements.

- **Payment Mechanism 1: FFS payment.**
- **Payment Mechanism 2: FFS payment plus a monthly infrastructure payment directly to the Next Generation ACO.** In addition to normal FFS reimbursement, the ACO receives an additional per beneficiary, per month payment not related to claims to invest in infrastructure to support ACO activities. This payment is no more than \$6 per beneficiary per month and is recouped in full by CMS during an annual reconciliation regardless of the Next Generation ACO's savings or loss. This requires a large financial guarantee to ensure that CMS can recoup this payment.
- **Payment Mechanism 3: Reduced FFS payment plus population-based payments to the Next Generation ACO.** CMS provides the Next Generation ACO with monthly population-based payments to support the ACO's activities and to allow the ACO to enter into arrangements with providers/suppliers. The ACO determines the percentage by which FFS payments to providers/suppliers is reduced and this projected aggregate amount is paid to the ACO in monthly payments. Providers/suppliers must agree to the reduction and must be providers/suppliers of the ACO.
- **Payment Mechanism 4: CMS makes capitated payments to the Next Generation ACO with some amount withheld for anticipated services providers by non-ACO providers/suppliers.** A Next Generation ACO participating in this model is responsible for paying claims to providers/suppliers and other affiliated providers according to written agreements. A Next Generation ACO may elect to collaborate with Capitation ACO Affiliates to participate in a capitated payment methodology. This option will become available in 2017.

#### IV. Savings/Loss Calculations

A Next Generation ACO's savings or losses will be determined by comparing actual Medicare Part A and Part B spending to the ACO's benchmark. The elected risk arrangement will determine the ACO's share of any saving or loss realized by the ACO. Payment or savings or recoupment of losses will follow an annual reconciliation. At this time, CMS will also account for monthly payments received by the ACO.

#### Beneficiary Alignment

An ACO must have a minimum number of 10,000 Medicare beneficiaries. Beneficiaries will be assigned on a prospective basis in the same process as currently used by Pioneer ACOs. In addition, CMS will allow Medicare beneficiaries to voluntarily become aligned to a Next Generation ACO. Beneficiaries will have the option of confirming or denying their relationship with the Next Generation ACO's providers/suppliers, which will supersede the claims-based alignment process. Next Generation ACOs will communicate directly with beneficiaries (subject to prior approval by CMS) to provide information regarding voluntary alignment and the services offered by the Next Generation ACO. CMS hopes that allowing beneficiaries to voluntarily align with a Next Generation ACO will mitigate fluctuations in the aligned beneficiary population. Beneficiaries will retain full freedom of choice of providers.

#### Benefit Enhancements

A central element of the Next Generation Model is the ability of Next Generation ACOs to engage in new activities to engage beneficiaries. CMS plans to waive certain Medicare payment requirements as part of the Next Generation Model to allow Next Generation ACOs to offer certain "benefit enhancements" to beneficiaries aligned with the ACO, provided there is a written agreement to that effect with the Preferred Provider that has been submitted to CMS. Enhancements include the following:

- **Beneficiary Coordinated Care rewards for beneficiary engagement.** CMS will finalize the size of payments to beneficiaries. CMS expects that the reward size will be \$50 per beneficiary per year, paid on a semiannual basis, and will be rewarded only if the beneficiary receives 50 percent of all Part A and Part B services from the Next Generation ACO's providers/supplier, preferred providers, and affiliates. Participation in this benefit enhancement will not be optional. The reward payments will be made automatically to beneficiaries.
- **Waiver of the three-day inpatient stay requirement prior to admission to a SNF or acute care hospital or critical access hospital.** Beneficiaries can be admitted to a SNF that is a qualified SNF ACO Affiliate either directly from home or with an inpatient stay of fewer than three days. The waiver will apply only if the beneficiary is admitted by an ACO provider/supplier or a Preferred Provider and the beneficiary meets certain SNF admission requirements. This benefit enhancement will be optional for Next Generation ACOs.
- **Waiver of telehealth payment limitations for telehealth services delivered by Next Generation ACO providers/suppliers or Preferred Providers to aligned beneficiaries at certain facilities or in the beneficiary's home.** This benefit enhancement will be optional for Next Generation ACOs.
- **Waivers to allow "incident to" claims for post-discharge home visits to non-homebound beneficiaries by licensed clinicians under general supervision (rather than direct supervision) of providers/suppliers or preferred providers.** The waivers will be allowed following discharge from inpatient facilities. This benefit enhancement will be optional for Next Generation ACOs.

#### Quality Measures, Performance Standards, and Reporting

The Next Generation Model will adopt the MSSP quality measure set without the electronic health record measure. CMS will conduct audits on ACO quality data. CMS will provide ongoing program performance and payment data to Next Generation ACOs.

#### Monitoring and Oversight by CMS

The Next Generation Model will require additional safeguards to protect against program integrity risks. The compliance plan requirements for the Next Generation Model are similar to the MSSP but also include a specific requirement that the ACO develop a quality assurance mechanism that includes a peer review process to investigate potential quality issues. CMS will monitor activities of Next Generation ACOs using means similar to those employed under the MSSP. Noncompliance with the CMS participation agreement will result in corrective action.

#### Application Process

CMS expects between 15 and 20 ACOs to participate in the Next Generation Model. Applications will be accepted in two rounds: the first round due date is June 1, 2015 (Round One) and the second is June 1, 2016 (Round Two). ACOs selected in Round One will have an initial agreement term (expected to begin January 1, 2016) of three one-year performance periods with the potential for two one-year extensions. ACOs selected in Round Two will have an initial agreement term (expected to begin January 1, 2017) of two one-year performance periods, with the potential for two one-year extensions. Current participants in the MSSP or Pioneer ACO Model may apply for participation in the Next Generation Model. Such applicants will be required to demonstrate good performance and conduct in their current or previous ACO model.

ACOs interested in applying in Round One must submit a letter of intent by 11:59 p.m. on May 1, 2015.

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<sup>1</sup> Unlike the MSSP, the preliminary information regarding a Next Generation ACO's governing body does not

provide an alternative means of involving a Medicare beneficiary in the ACO's leadership.

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## **OIG REJECTS PROPOSED LABORATORY-PHYSICIAN PRACTICES REFERRAL ARRANGEMENT**

The Office of Inspector General (OIG) recently issued an [Advisory Opinion](#) regarding the validity of a proposed arrangement (Proposed Arrangement) under which a medical laboratory (Laboratory) sought to provide free services to certain patients of physician practices to secure referrals of all business from the physician practices, including business generated by federal health care program beneficiaries.

The OIG concluded that the Proposed Arrangement could potentially generate prohibited remuneration under the anti-kickback statute (AKS) and could result in administrative sanctions. The OIG further concluded that the Proposed Arrangement could violate the Social Security Act's (Act) "substantially-in-excess" prohibition, resulting in grounds for potential exclusion from Medicare and Medicaid. The Advisory Opinion highlights several features of the Proposed Arrangement that raise concerns about its permissibility.

### **The Proposed Arrangement**

Under the Proposed Arrangement, the Laboratory would enter into referral agreements with physician practices to provide all laboratory services required by the physician practices' patients. The Laboratory would bill all patients, whether privately insured or covered by a Federal health care program, in accordance with fee schedules or contracted rates unless a patient's insurance required the use of a different laboratory. Where a patient's insurance required use of a different laboratory, the Laboratory would not bill the patient, the physician practice, or any insurer for laboratory services provided.

In addition, the Laboratory would provide physician practices participating in the Proposed Arrangement with a limited-use interface for the transmission of laboratory orders and results. Aside from the interface, the Laboratory certified that it would provide no items, services, or financial benefits to physician practices under the Proposed Arrangement. In defending the Proposed Arrangement, the Laboratory noted that the OIG has previously stated that the provision of a limited-use interface similar to that provided by the Laboratory does not constitute "remuneration" for purposes of the AKS.

### **Anti-Kickback Statute**

The AKS makes it a crime to knowingly and willfully offer or receive remuneration to induce or reward referrals of items or services reimbursable by a federal health care program. The OIG has consistently taken the position that arrangements involving the provision of free or below-market goods or services to actual or potential referral sources are suspect and may violate the AKS. Although the physicians and physician practices would not receive any direct payments under the Proposed Arrangement, the OIG identified certain aspects of the Proposed Arrangement that, in combination, could amount to prohibited remuneration from the Laboratory to the physician practices. First, the OIG noted that physician practices had apparently expressed a desire to work with a single laboratory for ease of communication and consistency in reporting test results. Second, the OIG explained that some electronic medical record system vendors charge physician practices a monthly maintenance fee in connection with interfaces used to transmit orders and results to various laboratories. The OIG therefore determined that the Proposed Arrangement could relieve participating physician practices of such expenses associated with laboratory interfaces that the physician practice would no longer have to maintain. The OIG concluded that it could not rule out with sufficient confidence the possibility that the Laboratory would be offering remuneration in the form of reduced administrative and financial burdens associated with using a single laboratory to induce the referral of federal health care program beneficiaries. The OIG further noted that there are no discernable quality or safety improvements to be gained by reducing these burdens nor are there any other safeguards that would make this remuneration low risk under the AKS; rather, the Proposed Arrangement could result in inappropriate steering of federal health care program beneficiaries.

### **Substantially-In-Excess Provision**

The OIG expressed additional concern that the Proposed Arrangement could constitute grounds for

permissive exclusion from Medicare and Medicaid by violating the Act's substantially-in-excess provision, which prevents individuals and entities from charging Medicare and Medicaid substantially more than rates usually charged to other payors for the same services. The OIG determined that the Proposed Arrangement essentially creates a two-tiered pricing structure by completely relieving certain patients and their insurers of any obligation to pay in return for the Laboratory pulling through all of a physician practice's federal health care program business, which would be charged at the full rate. While the OIG could not definitively determine whether the Laboratory would violate the substantially-in-excess provision without reviewing data from each physician practice, which is outside the scope of the advisory opinion process, the OIG concluded that it could not grant the Proposed Arrangement prospective immunity because it poses too high of a risk of violating the substantially-in-excess provision.

### **OIG Scrutiny of Laboratory Arrangements**

The OIG's refusal to sanction the Proposed Arrangement is the most recent example of its longstanding fraud and abuse concerns associated with laboratories. For example, in July 2014, the OIG issued a [Special Fraud Alert](#) in which the agency cautioned health care entities about "inherently suspect" arrangements under the AKS involving payments to physicians for processing of laboratory specimens and the compilation of patient registries.

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### **RHODE ISLAND COURT OVERTURNS CON APPROVAL OF ASC'S LICENSURE CHANGE**

On March 18, 2015, a Rhode Island Superior Court [reversed](#) a Rhode Island Department of Health (DOH) decision to grant a certificate of need (CON) application filed by Endoscopy Associates, Inc. (Endoscopy Associates) in a case that highlights the challenges posed by CON laws for health care entities seeking to keep pace with changes in the health care industry.

Endoscopy Associates' CON application requested approval for a corporate restructuring under which its license would change from a physician ambulatory surgery center (Physician ASC) to a freestanding ambulatory surgery center (Freestanding ASC). A Freestanding ASC license provides more flexibility in ownership and operations than a Physician ASC license, including by allowing nonphysician ownership and nonowner physicians to practice in a Freestanding ASC. Endoscopy Associates sought such flexibility in anticipation of systemic changes in the health care system. The DOH approved Endoscopy Associates' CON application in 2013, only to be overturned by a hearing officer (Hearing Officer) from Rhode Island's Department of Administration. The Hearing Officer reviewed the DOH decision after a third party requested a reconsideration on the basis that Endoscopy Associates failed to meet its burden for demonstrating an unmet public need, which is required for CON approval in Rhode Island. In overturning the DOH decision, the Hearing Officer noted that Endoscopy Associates' application to change its licensure was not covered or anticipated by Rhode Island's CON process.

Endoscopy Associates then sought judicial review of the DOH decision in Rhode Island Superior Court, in accordance with Rhode Island agency procedure. The court observed that granting a CON application requires a finding of a "substantial or obvious community need" and noted that Endoscopy Associates' CON application was "unique" in that it only sought permission for a license change. The court further observed that Endoscopy Associates conceded its current structure satisfies the existing community need and would continue to do so if the CON application were denied. The court determined that there was a complete absence of evidentiary support for the proposition that changing Endoscopy Associates' licensure would fulfill a community need. The court therefore concluded that the DOH decision was clearly erroneous in view of the evidence present in the record and remanded the CON application for reconsideration by the DOH. The court, echoing the Hearing Officer, did find that the CON process is not tailored to an application of the type put forward by Endoscopy Associates but stated that it is the responsibility of Rhode Island's legislature to address this issue.

Robinson+Cole will monitor the DOH's reconsideration of Endoscopy Associates' CON application as well as the impact the court's decision may have on the CON process in Rhode Island.

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If you have any questions, please contact a member of  
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