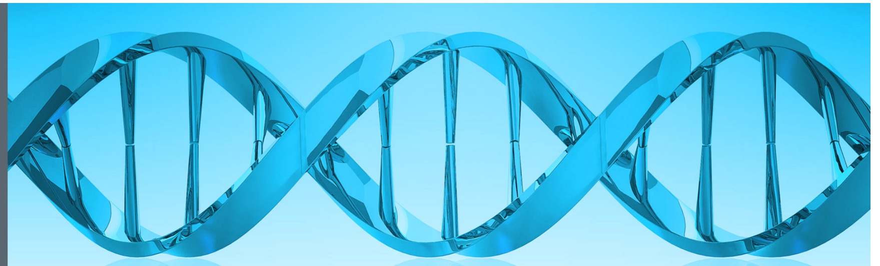
POLSINELLI

in the news

Health Care



April 2015

Accountable Care Organization Update

In this Issue:

I. Summary of Next Generation ACO Model. 1

II. Summary of Additional Guidance on ACO Pre-Participation & Participation Waivers 6

For More Information 7

About Polsinelli's Health Care Practice 8

On March 10, 2015, the U.S. Department of Health and Human Services announced a new accountable care organization ("ACO") initiative from the Centers for Medicare & Medicaid Services ("CMS") Innovation Center – the Next Generation ACO Model (the "Next Generation Model").

The Next Generation Model builds on experiences with the Pioneer ACO Model and the Medicare Shared Savings Program ("MSSP"), but is intended to set more predictable financial targets to enable providers and beneficiaries greater opportunities to coordinate and provide high quality care. The stated goal of the Next Generation Model is to "test whether strong financial incentives for ACOs, coupled with tools to support better patient engagement and care management, can improve health outcomes and lower expenditures for Original Medicare fee-for-service ("FFS") beneficiaries."

The announcement of the Next Generation Model follows a flurry of activity from CMS related to the MSSP, including its release of Notice of Proposed Rulemaking (and comment period) and issuance of additional guidance on certain requirements of the ACO Pre-Participation and Participation Waivers (summarized below). CMS has not indicated what, if any, impact the Next Generation Model will have on the MSSP or any of its other shared savings initiatives.

The following is a general overview of the Next Generation Model and MSSP additional guidance on certain requirements of the ACO Pre-Participation and Participation Waivers:

I. Summary of Next Generation ACO Model.

1. Application Process. The Next Generation Model will have two rounds of applications with submission due dates and Participation Agreement periods as follows:

	Letter of Intent Due Date	Application Due Date	Participation Agreement Period
Round One	May 1, 2015	June 1, 2015	Initial agreement of three 1-year performance periods, with the potential of two additional 1-year extensions
Round Two	May 1, 2016	June 1, 2016	Initial agreement of two 1-year performance periods, with a potential of two additional 1-year extensions

CMS will evaluate the applications it receives based on criteria in five key areas, including: (a) organizational structure; (b) leadership and management; (c) financial plan and experience with risk sharing; (d) patient centeredness; and (e) clinical care model.

Notably, an ACO currently participating in the MSSP or the Pioneer ACO Model that demonstrates good performance and conduct is eligible to apply for the Next Generation Model. *However*, an ACO may *not* concurrently participate in the Next Generation Model and other shared savings initiatives (i.e., MSSP, Comprehensive ESRD Care Initiative, Comprehensive Primary Care Initiative, or Pioneer ACO Model).

CMS expects to accept approximately 15 to 20 ACOs into the Next Generation Model, but has indicated its willingness to accept more depending on the number and quality of applicants.

2. Eligible Providers/Suppliers, Preferred Providers, and Affiliates. A Next Generation Model ACO may have relationships with the following:

a) **Eligible Providers/Suppliers**. Next Generation Model ACOs may be formed by Medicare enrolled providers and/or suppliers structured as: physicians or other practitioners in group practice arrangements, networks of individual physicians or other practitioners, hospitals employing physicians or other practitioners, partnerships or joint venture arrangements between hospitals and physicians or other practitioners, Federally Qualified Health Centers, Rural Health Clinics, and Critical Access Hospitals. It is important to note that the TIN of a Next Generation Provider/Supplier may *not* concurrently participate in the Next Generation Model and the MSSP. Within the Next Generation Model, an individual provider designated as a primary care provider may *not* concurrently participate as a Next Generation Provider/Supplier in multiple Next Generation Model ACOs.

b) **Preferred Providers**. This is a new concept for the Next Generation ACO Model. Preferred Providers will contribute to ACO goals by extending and facilitating valuable care relationships beyond the ACO. An ACO may allow certain benefit enhancements available to aligned beneficiaries to be available through Preferred Providers if the ACO has a written agreement with the Preferred Provider and placed them on the Preferred Provider list. A Preferred Provider is *not* a Provider/Supplier and will *not* be considered in beneficiary alignment. A Preferred

© 2015 Polsinelli

Provider *may* also participate in other shared savings programs and multiple Next Generation Model ACOs.

c) **Next Generation Affiliates**. There are two types of Next Generation Affiliates, as follows:

i. *Capitation Affiliates*. Medicare providers/suppliers with whom an ACO contracts to participate in capitation with regard to Next Generation beneficiaries.

ii. *SNF Affiliates*. SNFs to which Next Generation Providers/Suppliers or Preferred Providers may admit according to the SNF 3-day rule benefit enhancement.

Affiliates are *not* Providers/Suppliers and will not be considered in beneficiary alignment. An Affiliate *may* also participate in other shared savings programs and multiple Next Generation Model ACOs.

3. Organization and Governance. The Next Generation Model includes legal entity, governance structure, and leadership requirements similar to the MSSP. For example, the Next Generation Model ACO must be organized as a legal entity (and will be deemed to meet the legal entity requirement if participated in the MSSP or Pioneer ACO Model in the prior year). In addition, at least 75 percent of the ACO's governing body must be held by Next Generation Providers/Suppliers or their designated representatives, at least one Medicare beneficiary, and at least one consumer advocate (who may also be the Medicare beneficiary). The ACO governing body must also have a conflict of interest policy approved by CMS.

4. Financial Benchmark, Payment Mechanisms, and Shared Savings. The Next Generation Model has higher levels of risk and reward than the MSSP or the Pioneer ACO Model, as follows:

a) **Benchmark.** Unlike the MSSP and Pioneer ACO Model, in which the final updated benchmark is determined at the end of each performance year, CMS will prospectively establish the Next Generation Model benchmark prior to the start of each performance year using the expenditure, quality and risk score data available at the time of the benchmark setting.

For Performance Years 1 through 3, CMS will set the benchmark through a 4-step process, as follows:

i) The ACO's baseline will be determined using one year of historic expenditures.

ii) The baseline will be trended forward using a regional projected trend.

iii) The baseline and performance year populations will be risk adjusted using the full CMS Hierarchical Condition Category risk score and allowed to increase or decrease up to a maximum of 3 percent between the baseline and performance years.

iv) In contrast to the Pioneer ACO Model and MSSP, the Next Generation ACO Model will *not* utilize a minimum savings rate. A discount will be applied to the trended and risk-adjusted baseline to calculate the performance year benchmark. The total discount will range from 0.5 percent to 4.5 percent and will be derived from one quality adjustment and two efficiency adjustments (regional and national).

For Performance Years 4 and 5, CMS will provide the details of an alternative benchmarking methodology no later than the end of 2017 that will be based on

© 2015 Polsinelli

certain principles, including – for example – taking into account public comments received in response to the MSSP Notice of Public Rulemaking on alternative benchmark approaches or considering the use of a normative trend.

b) **Risk Arrangements**. The Next Generation Model will offer a choice of two risk arrangements, as described below. In both risk arrangements, the sharing rate will be higher than those in the MSSP or Pioneer ACO Model.

Arrangement A – Increased Shared Risk	Arrangement B – Full Performance Risk
PY1 through PY3 – 80 percent sharing rate	100 percent risk for Parts A & B
PY4 & PY5 – 85 percent sharing rate	15 percent savings/losses cap
15 percent savings/losses cap	Discount
Discount	

c) **Payment Mechanisms**. The Next Generation Model will also offer a selection of alternative payment mechanisms to enable a graduation from FFS reimbursements to full capitation, as follows:

i) Normal FFS Payment – No change from Original Medicare.

ii) Normal FFS Payment Plus Monthly Infrastructure Payment – Providers/Suppliers receive normal FFS reimbursement and the Next Generation Model ACO will receive an additional payment of up to $6 PBPM for infrastructure throughout the year without requiring the ACO to take on a claims-paying function. The Infrastructure Payment will be recouped in full from the ACO during the reconciliation process regardless of savings or losses. The ACO will be required to have in place a sufficiently large financial guarantee to assure repayments to CMS.

iii) Population-Based Payment ("PBP") – This is a current option for Pioneer ACO Model ACOs. Medicare payment redistributed through FFS and PBPM payment to ACO by determining a percentage reduction to the base FFS payments to the Providers/Suppliers (must agree to this) and paying the projected total annual amount taken out of the base FFS rates in monthly payments.

iv) Capitation – Becomes available in Performance Year 2. CMS will estimate the total annual expenditures for Next Generation Beneficiaries and pay that projected amount to the ACO in a PBPM payment with some money withheld to cover anticipated care by non-ACO Providers/Suppliers. The ACO will be responsible for paying claims for its Providers/Suppliers and Capitation Affiliates with whom the ACO has written agreements regarding capitation.

d) **Savings/Losses Calculation**. A Next Generation Model ACO's savings or losses will be determined by comparing total Parts A and B spending for Next Generation Beneficiaries to the Benchmark. The Risk Arrangement (Arrangement A or B) determines the ACO's share of savings or losses. This will occur annually following a year-end financial reconciliation.

It is also important to note that ACOs will be required to have in place financial guarantees sufficient to cover potential losses and will be required to comply with all applicable state regulations regarding provider-based risk-bearing entities.

POLSINELLI

real challenges. real answers. SM

© 2015 Polsinelli

5. Beneficiary Eligibility and Alignment. Next Generation Model ACOs must maintain at least 10,000 minimum Medicare beneficiaries *except* rural ACOs are permitted to have only 7,500 Medicare beneficiaries. During the base or performance year, the beneficiary must meet certain eligibility criteria to be aligned or attributed.

Eligible beneficiaries will be aligned as follows:

a) **Claims-Based Alignment**. The Next Generation Model will use the same methodology as the Pioneer ACO Model to prospectively align beneficiaries to Next Generation Model ACOs. This methodology uses a two -stage alignment algorithm. First, CMS will analyze claims for all beneficiaries who received care from Providers/Suppliers to determine the percentage of each beneficiary's outpatient E&M services in select primary care specialties. Second, CMS will focus on beneficiaries with less than 10 percent of their E&M services delivered by Next Generation Model ACO primary care providers – a determination that Providers/Suppliers in select subspecialties was central to a beneficiary's care may result in alignment.

b) **Voluntary Alignment**. In addition to claims-based alignment, CMS will offer beneficiaries an opportunity to become aligned voluntarily. During PY1 and annually in PY2 through PY4, Next Generation Model ACOs may offer currently and previously aligned beneficiaries the opportunity to confirm or deny care relationships with specific Providers/Suppliers. The confirmation of care relationships will supersede claims-based attribution. ACOs will be required to send a CMS-approved letter directly to beneficiaries with information regarding voluntary alignment and potential benefit enhancements associated with alignment to Next Generation Model ACOs.

6. Benefit Enhancements. A Next Generation Model ACO may choose whether to implement any or all of the following benefit enhancements:

a) **3-Day SNF Rule Waiver**. This is consistent with the Pioneer ACO Model waiver. This waiver will permit eligible aligned beneficiaries to be admitted to qualified SNF Affiliates by Providers/Suppliers or Preferred Providers either directly or with an inpatient stay less than 3 days.

b) **Telehealth Expansion**. This waiver will permit telehealth services for beneficiaries even if not located in rural areas by waiving the requirement that beneficiaries be located in a rural area and at a specified type of originating site in order to be eligible to receive telehealth services.

c) **Post-Discharge Home Visit**. This waiver will permit "incident to" claims for home visits to non-homebound beneficiaries by licensed clinicians under general supervision instead of direct supervision of Providers/Suppliers or Preferred Providers.

d) **Beneficiary Coordinated Care Reward**. CMS will make direct payments to each Next Generation Model ACO Beneficiary who receives at least a certain percentage of his or her Medicare services from Providers/Suppliers, Preferred Providers, and Affiliates. Next Generation Beneficiaries will automatically participate in this benefit enhancement and be eligible for this reward payment beginning in 2016. CMS expects that the reward amount will be approximately $50 per Beneficiary per year, paid semi-annually.

© 2015 Polsinelli

7. Quality and Performance. The Next Generation Model will adopt the MSSP quality domains, measures, benchmarking methodology, sampling, and scoring, *except* the EHR measure will *not* be adopted.

8. Monitoring and Oversight. Similar to the MSSP, the Next Generation Model ACOs will be required to develop a compliance plan, including having a compliance officer, and develop oversight mechanisms such as internal audits and corrective action plans, quality assurance strategy, compliance training programs, and anonymous reporting.

9. Data Sharing. CMS will honor data sharing opt-out decisions by beneficiaries while aligned in another initiative. However, the Next Generation Model ACO will not be required to notify newly aligned beneficiaries at the beginning of the performance year regarding the ACO's intent to request their claims data or to provide information or forms regarding the opportunity to decline data sharing. The ACO will receive monthly financial reports and quarterly utilization and expenditures reports.

II. Summary of Additional Guidance on ACO Pre-Participation & Participation Waivers.

On February 12, 2015, CMS and the Office of Inspector General ("OIG") issued additional guidance on certain requirements of the ACO Pre-Participation and Participation Waivers applicable to accountable care organizations ("ACOs") participating in the Medicare Shared Savings Program ("MSSP"), as follows:

1. Public Disclosure of Arrangements under the ACO Pre-Participation and ACO Participation Waivers. CMS/OIG finalized the requirements for the method and content of the public disclosures of an arrangement for which ACO Pre-Participation and ACO Participation Waiver protection is sought, as follows:

a) A description of the arrangement must be posted on a public website belonging to the ACO (or an individual or entity forming the ACO for purposes of the ACO Pre-Participation Waiver) within 60 days of the date of the arrangement.

b) The website must include the name of the ACO and other information that will allow a search to easily locate the website and identify where the arrangements are posted.

c) The arrangement must be clearly labeled as an arrangement for which waiver protection is sought.

d) The description of the arrangement must include – (i) information identifying the parties to the arrangement; (ii) date of the arrangement; and (iii) the type of item, service, good or facility provided under the arrangement.

e) If a material amendment or modification to a previously disclosed arrangement, the amendment or modification should be disclosed in the same manner and identified as an amendment or modification.

f) The financial or economic terms of the arrangement should not be included.

2. Notification of failure to submit a timely application by parties who used the ACO Pre-Participation Waiver. CMS/OIG provided guidance on the notice process for an ACO that claims protection under the Pre-Participation Waiver but does not submit an application for a participation agreement under the MSSP by the last available application due date. The ACO must submit a statement that includes, at a minimum, a description of the reasons that the ACO was unable to

© 2015 Polsinelli

submit an application and certification by a legally authorized signatory that the information contained in the statement is true, correct, and accurate to the best knowledge of the signatory. The statement must be submitted electronically (in PDF format) to the CMS, Division of Technical Payment Policy at SSP_Preparticipation@cms.hhs.gov on or before the last available application due date for the target year. The submissions will be shared with the OIG.

3. Requests for an extension of the ACO Pre-Participation Waiver. Separate from the notice process described above, CMS/OIG also established a procedure for an ACO that claims protection under the Pre-Participation Waiver but is unable to submit an application to participate in the MSSP by the application due date to apply for an extension of the ACO Pre-Participation Waiver period. The ACO must demonstrate a likelihood of successfully developing an ACO by the next available application due date by including, at a minimum, a description of the diligent steps taken to develop an ACO, including the timing of actions undertaken and the manner in which the actions relate to the development of an ACO, any additional evidence demonstrating a likelihood of success, and a certification by a legally authorized signatory that the information is true, correct, and accurate. The request must be submitted electronically (in PDF format) to the CMS, Division of Technical Payment Policy at SSP_Preparticipation@cms.hhs.gov no later than 60 days prior to the selected application due date. The requests will be shared with the OIG.

For More Information

For more information regarding this alert, please contact the author, a member of the Polsinelli's Health Care practice, or your Polsinelli attorney.

- Janice Anderson | *Author* | 312.873.3623 | janderson@polsinelli.com
- Joi-Lee K. Beachler | *Author* | 214.661.5532 | jbeachler@polsinelli.com

To contact a member of our Health Care team, click here or visit our website at www.polsinelli.com > Services > Health Care Services > Related Professionals.

To learn more about our Health Care practice, click here or visit our website at www.polsinelli.com > Services > Health Care Services.

© 2015 Polsinelli

About Polsinelli's Health Care Practice

The Polsinelli Health Care practice comprises one of the largest concentrations of health care attorneys and professionals in the nation. From the strength of its national platform, the firm offers clients a depth of resources that cannot be matched in their dedication to and understanding of the full range of hospital-physician lifecycle and business issues confronting health care providers across the United States.

Recognized as the "Law Firm of the Year" in Health Care for 2015 by *U.S. News & World Report*, Polsinelli is ranked no. 2 by The American Health Lawyers Association and no. 3 by *Modern Healthcare*.* Polsinelli's highly trained attorneys work as a fully integrated practice to seamlessly partner with clients on the full gamut of issues. The firm's diverse mix of seasoned attorneys well known in the health care industry, along with its bright and talented young lawyers, enables our team to provide counsel that aligns legal strategies with our clients' unique business objectives.

**AHLA Connections* and *Modern Healthcare* (June 2014).

About Polsinelli

real challenges. real answers.[SM]
Polsinelli is a first generation Am Law 100 firm serving corporations, institutions, entrepreneurs and individuals nationally. Our attorneys successfully build enduring client relationships by providing practical legal counsel infused with business insight, and with a passion for assisting General Counsel and CEOs in achieving their objectives. Polsinelli is ranked 18th in number of U.S. partners* and has more than 740 attorneys in 20 offices. Profiled by *The American Lawyer* and ranked as the fastest growing U.S. law firm over a six-year period**, the firm focuses on health care, financial services, real estate, life sciences and technology, energy and business litigation, and has depth of experience in 100 service areas and 70 industries. The firm can be found online at www.polsinelli.com. Polsinelli PC. In California, Polsinelli LLP.

* *Law360*, March 2014
** *The American Lawyer* 2013 and 2014 reports

About this Publication

Polsinelli provides this material for informational purposes only. The material provided herein is general and is not intended to be legal advice. The choice of a lawyer is an important decision and should not be based solely upon advertisements.

Polsinelli PC. In California, Polsinelli LLP.

© 2015 Polsinelli