I. Introduction

A. Overview: Medicare Shared Savings Program

1. The Centers for Medicare & Medicaid Services (CMS) has established a Medicare Shared Savings Program (MSSP) to facilitate coordination and cooperation among providers to improve the quality of care for Medicare Fee-For-Service (FFS) beneficiaries and to reduce unnecessary costs. Eligible providers, hospitals, and suppliers may participate in the MSSP by creating or participating in an Accountable Care Organization (ACO).

2. ACOs are groups of doctors, hospitals, and other health care providers who come together voluntarily to give coordinated, high quality care to the Medicare patients they serve. Coordinated care helps ensure that patients—especially the chronically ill—get the right care at the right time, with the goal of avoiding unnecessary duplication of services and preventing medical errors.

3. The MSSP is designed to improve beneficiary outcomes and increase the value of care by:
   
   a) Promoting accountability for the care of Medicare FFS beneficiaries
   
   b) Requiring coordinated care for all services provided under Medicare FFS; and
   
   c) Encouraging investment in infrastructure and redesigned care processes.

4. The MSSP will reward ACOs that lower their growth in health care costs while meeting performance standards on quality of care and putting patients first. Participation in an ACO is purely voluntary.
5. Shared Savings: As part of the program, if investments generate savings for the Medicare program, ACOs may share in a portion of the savings based on financial and quality performance. However, ACOs may also be required to repay Medicare for shared losses. ACOs can therefore choose to participate under a Track 1 “shared savings only” model (one-sided model) or a Track 2 “shared savings and losses” model (two-sided model). Although the 2 models share many common features, such as eligibility requirements, quality measures and shared savings methodology, ACOs that decide to participate under Track 2 are accountable for shared losses, but also have the opportunity for a greater percentage of shared savings than Track 1 participants.

B. Overview: Pioneer ACO Program

1. Working in concert with the Shared Savings Program, the CMS Innovation Center is currently testing an alternative ACO model: the Pioneer ACO Model. This initiative is designed to support organizations with a new payment model, allowing them to provide more coordinated care to beneficiaries at a lower cost to Medicare. The Pioneer ACO Model was designed specifically for health care organizations and providers with experience offering coordinated, patient-centered care, and operating in ACO-like arrangements. The Model will allow these provider groups to move more rapidly from a shared savings payment model to a population-based payment model on a track consistent with, but separate from, the Medicare Shared Services Program. Ultimately, the model is designed to work in coordination with private payers by aligning provider incentives, which will improve quality and health outcomes for patients across the ACO, and achieve cost savings for Medicare, employers and patients.

2. The Pioneer ACO Model is currently testing the impact of several innovative payment arrangements to support 23 organizations (selected through an open and competitive process) in achieving the goals of better care and outcomes at a lower cost. The 23 selected organizations were chosen for their significant experience offering this type of quality care to their patients, along with other criteria listed in the Request for Applications (RFA) documents.

II. Early ACO Results

A. MSSP

3. On January 30, 2014, CMS announced interim financial reconciliation results for MSSP performance year one. Overall, the preliminary financial data demonstrated mixed results.
4. According to these results, in their first 12 months, nearly half (54 out of 114) of the ACOs that started program operations in 2012 had lower expenditures than projected. Of the 54 ACOs that exceeded their quality reporting benchmarks in the first 12 months, 29 generated shared savings totaling more than $126 million\(^1\), yet it is unclear if the savings were offset by any losses from the remaining 60 MSSP participants. As noted above, ACOs share with Medicare any savings generated from lowering the growth in healthcare costs while meeting standards for high quality care.

5. Analysis of the Results: Many ACOs probably did not realize first year savings because they spent significant time and resources establishing the processes that may lead to lower costs in the future. “ACOs needing to make significant changes, particularly those that had minimal experience coordinating care, were most likely to be slow to develop these new competencies which would limit their ability to lower costs.”\(^2\)

B. Pioneer

1. According to an independent preliminary evaluation of the Pioneer ACO Model, Pioneer ACOs generated gross savings of $147 million in their first year while continuing to deliver high quality care.\(^3\) Results showed that of the 23 Pioneer ACOs, nine had significantly lower spending growth relative to Medicare fee-for-service while exceeding quality reporting requirements.\(^4\) Examples of the high quality care provided by the Pioneer ACOs include:

   a) Readmissions: A majority of the Pioneer ACOs generated lower risk-adjusted readmission rates for their aligned beneficiaries than the benchmark rate for all Medicare fee for service beneficiaries.

   b) Blood Pressure Control: Pioneer ACOs performed better on clinical quality measures that assess hypertension control for patients.

   c) Cholesterol Control for Patients with Diabetes: Pioneer ACOs performed better on clinical quality measures that assess low density lipoprotein (LDL) control for patients with diabetes.\(^5\) Developments for the Pioneer ACO Model:


\(^2\) [Link](http://healthaffairs.org/blog/2014/02/04/medicare-acos-mixed-initial-results-and-cautious-optimism/)

\(^3\) [Link](http://innovation.cms.gov/Files/reports/PioneerACOEvalReport1.pdf)

\(^4\) Id.

2. CMS has solicited comments on a Request for Information concerning a possible second round of applications to the Pioneer ACO Model. The Request for Information asks several questions, including about whether additional health care organizations would be interested in applying to the Pioneer ACO Model, Pioneer’s ability to transition to population-based payments, the evolution of the ACO Model (i.e., transition to greater insurance risk), and multi-payer ACOs.

III. Perspective on the challenges and rewards for participating in the Medicare ACO programs

A. Challenges

1. Financial-related. A number of organizations have attempted to quantify the financial costs of creating an ACO. Most reports on ACO startup costs, including one published by the American Hospital Association and another included in the CMS proposed ACO rule, have been based on prospective estimates of costs. Now that Pioneer and MSSP ACOs have some operational history, actual cost survey data have recently become available. The estimates and survey results on startup costs have varied greatly, including due to differences based on ACO size, but all indicate that the cost of establishing and commencing the operations of an ACO is substantial.

a) In a report published in January 2014, the National Association of ACOs (“NAACOS”) reported that the average startup costs for 35 surveyed ACOs were $2 million. The costs incurred by the survey respondents ranged from $300 thousand to $6.7 million.

b) In the proposed ACO rule, CMS estimated that a “rough estimate” of startup costs required for ACOs would be $1.755 million. CMS based its estimate on data obtained from participants in the ACO-like Physician Group Practice Demonstration Program. In preparing this estimate, CMS recognized that costs would vary widely based on factors such as the size and structure of the ACO, the pre-implementation infrastructure of the ACO, and the ability of the participants to access capital.

c) The American Hospital Association (“AHA”) published a report in April 2011 in which it attempted to estimate ACO startup costs based on two hypothetical “prototype” ACOs. Under Prototype A, the AHA

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6 http://innovation.cms.gov/Files/x/Pioneer-RFI.pdf


assumed a 200 bed, one hospital system, with 80 primary care physicians, and 150 specialists. For this prototype, the AHA estimated startup costs of $11.6 million. For Prototype B, the AHA assumed a 1,200 bed, five hospital system, with 250 primary care physicians, and 500 specialists. For this prototype, the AHA estimated startup costs at $26 million. The AHA identified a number of expense categories for developing ACOs, including: network development and management; care coordination, quality improvement, and utilization management; clinical information systems; and data analytics.

d) While ACOs will incur significant development costs and initial operating expenses, they will not receive any revenue for an extended period of time. Even assuming that an ACO achieves shared savings payments following the first performance year of its agreement with CMS, a newly established ACO could go two years or more without revenue. However, many ACOs will not obtain shared savings payments after their first performance year, some may never achieve a shared savings payment, and others may be required to share in losses with CMS under the Track 2 model.

e) Due to the combination of high initial expenses and a delayed revenue stream, many ACOs may not become profitable until the last year or years of their agreements with CMS.

f) During this time period, ACOs must have access to capital to finance the organization for extended period of startup time. NAACOS has estimated that the average ACO will require $4 million in startup capital prior to achieving profitability.\(^\text{10}\)

(1) ACO participants, particularly small physician practices and solo physicians, may have limited tolerance for an extended period of cash burn prior to the ACO receiving any revenue.

(2) The typical sources for funding startup costs are capital contributions by the owners and loans from banks. Obtaining a bank loan can be somewhat difficult if the lender is not experienced with evaluating health care businesses generally, or with ACOs specifically.

(3) Certain rural and physician-based ACOs are eligible for CMS’s Advance Payment ACO Model. Under this model, the ACOs can elect to receive advance payments of shared savings that are ultimately offset against the ACOs’ actually achieved annual shared savings payments. If the ACO does not generate sufficient savings to offset the advance payments it receives, CMS will

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\(^{10}\) National ACO Survey at 2.
continue to offset the advances against future performance year
shared savings payments. If the ACO’s CMS agreement
terminates or expires without the ACO achieving sufficient savings
to fully offset the advance payments, CMS may recoup the
remaining advance payments from the ACO.\textsuperscript{11}

2. IT-related. Robust electronic medical records (“EMR”) systems and other
types of interoperable information technology among ACO participants are
critical to the ability of ACOs to function. EMR systems and other IT are
essential to clinical, financial, and operational success of the ACO. NAACOs has
summarized the role patient and claims data as follows:

“The success of the ACO program is largely dependent on the
timely transfer of patient information and coordination of care.
Further, the ACO requires accurate and timely data from CMS
identifying their aligned beneficiaries and claims for their services.
These data are valuable for evaluating subpopulations (i.e., patients
with highly prevalent conditions or multiple chronic conditions),
cost and utilization of services to identify areas of opportunity, and
most importantly determining whether or not the ACO is achieving
their financial goals.”\textsuperscript{12}

a) Implementing and adopting an EMR system is expensive for
individual providers. In the networked context of an ACO, the aggregate
costs of implementing EMR systems can be even more expensive. This is
because the ACO as a whole must not only have individual instances of
EMR systems established with each of its participants, but also must
establish interfaces among ACO participants. EMR interfaces can be
costly among users of the same EMR system, and even more expensive
when the interface must link EMR systems provided by different vendors.

b) Depending on the in-house expertise of the ACO’s IT personnel,
the ACO and/or its participants may be required to rely on costly reports
prepared by EMR or other IT vendors for data analysis and quality
reporting.

c) If the ACO will connect to a Health Information Exchange,
establishing this connection will add an additional EMR-related expense
to the ACO.

\textsuperscript{11} Advance Payment Accountable Care Organization Model: Fact Sheet, \textit{available at}

\textsuperscript{12} A Request for Improvement in the Data Partnership between CMS and ACOs, NAACOS (Jan. 2014), \textit{available at}
d) In the January 2014 NAACOs survey, 40% of the survey respondents identified working with CMS data as their top operational challenge in the first year.\textsuperscript{13} NAACOs has identified the following specific challenges in working with CMS data:

(1) Beneficiary assignment: reconciling aligned beneficiary reports from CMS with internal patient records (e.g. different name spellings).

(2) Expenditure and utilization reports: lack of real-time data and a lack of detailed visibility to diagnoses and services related to expenses.

(3) Claims information: incomplete data due, for example, to the ability of ACO beneficiaries to opt out of data sharing and the exclusion of data related to substance abuse.

(4) Data reconciliation.\textsuperscript{14}

e) In addition to the financial challenges associated with implementing an interoperable EMR network among ACO participants, the implementation and use of the network poses operational challenges, including the compatibility of the participants’ EMR systems. Ideally, all ACO participants would operate under the same EMR system. If it is impossible to use a uniform system, minimizing the number of interfaces among different EMR systems already adopted by participants will save costs and make data sharing smoother.

3. Contracting / Corporate Governance

a) Merging existing corporate structure into MSSP requirements

(1) Even though MSSP regulations give flexibility, ACOs face challenges in revising their corporate structure and corporate governance to meet MSSP requirements.

(2) Regulatory Requirements: CMS regulations, specifically 42 C.F.R. § 425.106 impose significant requirements on the governing board to ensure shared governance of the ACO. Among other important requirements the ACO governing board must:

(a) Have oversight responsibility over ACO;

\textsuperscript{13} National ACO Survey at 3.

\textsuperscript{14} A Request for Improvement in the Data Partnership between CMS and ACOs at 2.
(b) Have a transparent governing process;

(c) Have members with a fiduciary duty to the ACO;

(d) Be separate and unique where ACO comprises multiple, otherwise independent ACO Participants;

(e) Allow for meaningful participation by ACO members;

(f) Include a beneficiary on the board;

(g) Be at least 75 percent controlled by ACO participants; and

(h) Have a conflict of interest policy.


(a) Guidance was posted on CMS website shortly after ACO program rules were finalized: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/Memo_Additional_Guidance_on_ACO_Participants.pdf

(b) This guidance provides additional explanation regarding the governing board’s fiduciary duty to the ACO.

(c) The governing body cannot meet the fiduciary duty requirement if the governing body is also responsible for governing the activities of individuals or entities that are not part of the ACO.

(d) This is particularly important for existing entities, like IPAs that wish to become the ACO. If the IPA has contracts with multiple providers, but not all of those providers will become ACO providers, the IPA cannot become the ACO. Further the governing board of the IPA cannot become the ACO governing board, because of CMS’s concern regarding conflicting fiduciary duties.

(e) As CMS has stated in this guidance document, “the ACO’s governing body decisions must be independent from influence of interests that may conflict with the ACO’s interests, including the interests of group practices.
that are not participating in the ACO but continue to be represented by the IPA for other purposes, such as commercial contracting.”

(4) Important Governance Considerations:

(a) Structure and participation of board: Do you have members that are representative of all interests of the ACO Participants?

(b) Medicare Beneficiary: Sometimes challenging to find the correct beneficiary, so plan accordingly.

(c) Conflict of Interest / Fiduciary Duty: While general corporate conflict of interest principles apply, be aware that CMS will evaluate the governance board structure closely, and ask questions as to whether interests of the board are fully aligned with the ACO’s goals.

b) Contracting with non-participant providers. Many ACOs will not be large enough or have enough specialized participants to meet all of the potential goals set by the ACO for providing care to aligned beneficiaries and containing costs. For this reason, many ACOs must contract with non-participant providers. Contracting with non-participants can be challenging because the financial considerations, rights, and obligations of the self-contained ACO participant network may not align perfectly with third parties.

(1) Paying non-participants. Determining how to pay non-participants for their services can be difficult because the ACO’s potential revenue is risk-based and indeterminate. Because non-participants do not have a direct interest in the upside or downside risk of an ACO agreement, they may be reluctant to accept anything other than a fee-for-service or time-based fee structure. However, because the ACO cannot precisely forecast its revenues, fixed fees for time spent or services provided by third-parties can expose the ACO to a potential over-commitment of resources. Some approaches to structuring payments for non-participant providers include:

(a) Fee-for-service or per time period.

(b) Per-member-per-month fees (if assigned responsibility for certain beneficiaries or populations with certain conditions).
(c) Allocation of shared savings contingent upon the third-party’s achievement of quality metrics and the receipt of shared savings payments by the ACO.

(d) Hybrids of (a) through (c).

(2) Establishing appropriate quality metrics for specific contracted providers. The non-participant providers with whom the ACO chooses to contract will likely be chosen because of their importance to the ACO’s ability to meet specific quality and cost targets that the participants collectively do not have the ability to meet within the structure of the ACO. Because non-participants will likely be chosen based on specific quality or cost objectives, it may make sense to hold the non-participants to quality and/or cost targets and offer bonuses and/or the potential for allocated share savings for meeting those objectives. In considering how to push down the ACO’s own quality and financial objectives to third parties, the following issues need to be addressed:

(a) Which metrics apply to which types of providers?

(b) Should the ACO establish additional condition-specific metrics that are not part of MSSP, but that will be beneficial to the ACO?

(c) When applying MSSP metrics, should non-participant providers be held to the same or higher performance standards than CMS requires of the ACO?

(d) If the non-participant provider is responsible for a specific subset of the ACO’s aligned beneficiaries, how will ACO assign and track those beneficiaries and the services provided to them by the non-participant?

B. Rewards

1. Participation in an ACO can offer providers a number of direct and indirect financial benefits:

a) Direct benefits. The potential direct benefits of participation in an ACO include the revenue received from shared savings payments and reduced internal costs incurred by the providers in delivering services.

b) Secondary benefits. Acceptance into a Medicare ACO program, and the realization of shared savings under a Medicare ACO program, requires ACOs and their participants to implement significant infrastructure, governance mechanism, processes, and protocols. However, once the infrastructure for a Medicare ACO program is in place,
the ACO and its providers can apply it to non-aligned Medicare beneficiaries and non-Medicare beneficiaries. If the underlying Medicare ACO framework is sound, it can be leveraged to:

(1) Reduce costs for non-Medicare ACO patients, and
(2) Obtain ACO or ACO-like agreements with commercial payors.

c) Other secondary benefits of participating in a Medicare ACO include reimbursement synergies with other Medicare policies. Several Medicare initiatives include enhanced reimbursement, or the avoidance of penalties, for meeting the same or similar metrics as those required under the MSSP. These initiatives include:

(1) CMS Hospital Readmissions Reduction Program,
(2) EHR Incentive Program,
(3) Hospital Value-Based Purchasing Program, and
(4) CMMI Models, such as Bundled Payments for Care Improvement, and the Comprehensive ESRD Care Initiative.

2. Participation in an ACO can offer providers a number of direct and indirect patient care quality benefits. The final MSSP rule includes 33 quality measures in the following categories: patient/caregiver experience, care coordination/patient safety, preventative health, and specific at-risk populations (e.g. diabetes, hypertension, ischemic vascular disease, heart failure, and coronary artery disease).15 Improving ACO participants’ performance in these categories can result in:

a) Healthier ACO beneficiaries,
b) Healthier non-ACO patients through application of quality initiatives, care coordination, and individual care planning developed in Medicare ACO context, and
c) Enhanced clinical integration among the ACO participants, through the discipline of the requirements of the Medicare ACO programs.

3. Fraud & Abuse Waivers

a) New waivers give ACOs and providers greater flexibility to enter into financial beneficial financial relationships without concern for Stark Law and Anti-Kickback prosecution.

b) Laws Covered by Waivers:
   (1) Physician Self Referrals Law (“Stark Law”).
   (2) Anti-Kickback Statute.
   (3) Civil Monetary Penalty Laws.
      (a) Prohibition on Hospital Payments to Physicians to Induce Reduction or Limitation of Services (“Gainsharing CMP”).
      (b) Prohibition on Inducements to Beneficiaries.

c) Waivers
   (1) Pre-Participation: For use before ACO is in operation.
   (2) Participation: For use when ACO is accepted into program.
   (3) Shared Savings Distribution: Applies to any distribution of shared savings within ACO and certain distributions outside of ACO.
   (4) Compliance with the Physician Self-Referral Law: Waives application of Anti-Kickback Statute when arrangement complies with the Stark Law.
   (5) Patient Incentive Waiver: Applies to medically related incentives offered to beneficiaries to encourage preventive care and compliance with treatment regimes.

IV. Discussion and analysis on the future of the Medicare ACO Programs and their impact on health care delivery, including commercial ACOs

A. Defining commercial ACOs.

1. Unlike in the context of a Medicare ACO, there are no legal or regulatory definitions or requirements for commercial ACOs. Therefore, what many refer to as commercial ACOs can take many forms, or else be more accurately described as non-fee-for-service contracts by ACOs with commercial payors. Although the
term “commercial ACO” is difficult to define, there appear to be approximately equal numbers of Medicare and non-Medicare ACOs in existence today.\(^{16}\)

2. Commercial ACO arrangements can include the following variations:

   a) Payor forms an ACO and offers as a product to beneficiaries and employers.

   b) Medicare ACO enters into some form of ACO contract with a payor.

   c) Medicare ACO and a payor enter into a joint venture to form a commercial ACO.

3. Examples of commercial ACO arrangements and contracts include:

   a) Shared savings and pay-for performance: bonuses and/or withholds based on achievement of cost and performance goals

   b) Capitated payments: partial or full.

   c) Case management fees.

   d) Bundled payments for episodes of care.

B. Incremental steps toward fully accountable care.

1. Because commercial ACOs are not as well-defined as the Medicare ACO Programs, they have more flexibility in designing:

   a) the ACO arrangement, and

   b) interim steps to move providers from fee-for-service payments to accountable care.

2. Examples of incremental steps to fully accountable care similar to a Medicare ACO:

   a) progressively increasing percentage of payment at risk based on quality and cost targets;

   b) expanding scope of care for which ACO is responsible (e.g. beginning with certain chronic disease states, expanding to all costs incurred for the patients); and

c) move from partial to full capitation.

3. Providers and payors can use data and experience gathered during interim steps to prepare for a smoother full ACO contract launch and more confidence in ability to succeed as an ACO.

C. Commercial payors are willing to work closely with ACO or ACO-like providers and networks to provide useful, customized patient health and cost data.

D. The Future of ACOs

1. First the Challenges

a) Fraud and Abuse

(1) The fraud and abuse waivers do not apply to commercial ACOs. Therefore, for those ACOs that are not in the MSSP, but that still trigger the Stark Law and Anti-Kickback Statute, they must fit within an exception and safe-harbor. While some arrangements will be protected, some creative financial arrangements may raise challenging questions under the Fraud & Abuse laws.

(2) Congressional Action. Since the waivers don’t apply to commercial ACOs and other integrated healthcare providers, new legal authority is necessary to create exceptions and safe harbors. Congress has begun to explore the necessity of these laws, yet more action will need to take place in order to pass this legislation.

(3) Will the waivers remain? In the MSSP waivers, CMS and OIG made a statement that they plan to narrow the waivers “unless information gathered through monitoring or other means suggests that the waivers . . . are adequately protecting the Medicare program and beneficiaries from the types of harms associated with referral payments or payments to reduce or limit services.” CMS and OIG must finalize the waivers by the fall of 2014, so we will soon see if the waivers are narrowed or kept in their current form.

(4) Aggressive prosecution may still stifle innovation for those entities that are “partially integrated.” Law enforcement agencies have recently focused their actions on physician compensation arrangements. See Tuomey and Halifax. These cases have created confusion and concern among healthcare providers regarding proper compensation structures. If these cases continue, health

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17 See Medicare Program; Final Waivers in Connection With the Shared Savings Program, 76 F.R. 67992, 68002 (Nov. 2, 2011).
care providers may be less willing to create integrated delivery systems.

b) Antitrust Enforcement. Recent activity by the Federal Trade Commission, such as action in Idaho against the St. Luke’s Health System, demonstrates that the antitrust agencies will not hesitate to enforce the antitrust laws against healthcare providers that participate in the MSSP program. Continued antitrust enforcement will lead some healthcare systems to question whether integration and participation in ACO programs are worth the potential risks that they could face in the future.

2. Path Forward and Important Questions

a) Medicare ACOs programs have been successful and popular. More than 360 ACOs have been created since the inception of the programs. And every year a higher number of ACOs are accepted into the program.

b) The MSSP and Pioneer Programs operate well and have been well managed by the government. Compared to other recent government programs created under the Affordable Care Act, like Healthcare.gov, the MSSP and Pioneer programs have been run well. There is an organized online application process, and CMS has been responsive to questions. While the scale of this program has probably made the process more manageable, it is still responsible for millions of Medicare beneficiaries, and therefore is a complex government program.

c) Will ACOs improve quality and reduce costs? Preliminary data demonstrates that the program will improve quality and reduce costs, but we need to wait for a few years to see if behavior and medical practice changes.

d) If it can’t reduce cost on its own, what will need to take its place?

(1) Shared losses. As discussed above, some ACOs are already liable for shared losses incurred for failing to meet established benchmarks. And those that are not currently accepting shared losses, will be accepting this new payment methodology in a few years. Some have argued that the only way that health care delivery will change is if providers don’t only receive financial incentives, but if they are at financial risk if they don’t achieve goals.

(2) Capitated Payment: Even though the MSSP is a program that uses financial incentives to change health care delivery, it is possible that behavior won’t change until providers are given capitated payments that provide a fixed sum of money for the care of individuals or populations. In addition to existing managed care
arrangements, both CMS and private payers are experimenting with these new payment structures, like bundled payments, and other fixed payment arrangements.