

The Medicare Shared Savings Program: A Focus on Compliance

By Gary Scott Davis, Lauren Haley, and Heather Last

¶25,500 Introduction

* Section 3022 of the Patient Protection and Affordable Care Act (PPACA)¹ requires the Secretary of the Department of Health and Human Services (HHS) to establish a Medicare Shared Savings Program (MSSP) designed to promote accountability for Medicare beneficiaries, improve coordination of Medicare fee-for-service (FFS) items and services, encourage investment in high quality and efficient service delivery through infrastructure and redesigned care processes, and motivate the provision of higher value care. On November 2, 2011, the Centers for Medicare & Medicaid Services (CMS) published a final rule implementing the MSSP through the formation of Medicare accountable care organizations (ACOs).²

The MSSP is built on the concept of CMS sharing with an ACO a portion of Medicare savings resulting from the ACO effectively coordinating care and achieving certain quality measures, each designed to improve the health of the ACO's patients. ACOs create incentives for health care providers to work together to treat Medicare patients across multiple care settings (i.e. the continuum of care). Designed to achieve a "triple aim"³ consisting of (1) better care for individuals; (2) better health for populations, and (3) lower growth in expenditures,⁴ (Triple Aim) the MSSP will reward ACOs that lower growth in health care costs and meet performance standards on quality of care.

This Chapter provides a high-level overview of the requirements ACOs must meet to participate in the

* Gary Scott Davis, P.A. is a partner at McDermott Will & Emery LLP, resident in the Miami, Florida office. A "Board Certified Health Law Attorney" as recognized by The Florida Bar Board of Legal Specialization and Education, he focuses his practice on managed care, emerging health benefit plans, strategic restructurings and reorganizations, joint ventures arrangements and related transactional, regulatory and reimbursement issues. He is also a Fellow (Inaugural Class) and a past member of the Board of Directors of the American Health Lawyers Association (AHLA). Mr. Davis is listed with the highest ranking as one of the leading health care attorneys in Florida by Chambers & Partners. He is the recipient of the AHLA's prestigious David J. Greenburg Service Award, and has been recognized by his peers for his expertise in health law in such publication as The Best Lawyers In America, Super Lawyers, Leading American Attorneys and The Best Attorneys Network. The National Law Journal has recognized him as one of the "National Leading Lawyers of Managed Care."

Lauren Haley is a partner at McDermott Will & Emery LLP, based in the firm's Washington, D.C., office. She focuses her practice on counseling health care organizations to comply with various legal and regulatory requirements that arise from participation in Medicare, Medicaid and other third-party payment programs. Before entering private practice, Ms. Haley gained significant experience as a health insurance specialist in the Program Integrity Group at CMS, where she had responsibilities for program integrity concerns inherent in the implementation of the Medicare Prescription Drug Benefit. In addition, Ms. Haley served as the director of government relations at the National Association for the Support of Long Term Care, a

trade association that represents providers and suppliers to long-term care settings.

Heather Last is an attorney with McDermott Will & Emery LLP and works with its Health Industry Advisory Practice Group out of the Miami, Florida office. Ms. Last focuses her practice on strategic restructurings and reorganizations, joint ventures arrangements and related transactional, regulatory and reimbursement issues. Prior to working with McDermott Will & Emery, Ms. Last held an in-house position with a health care company that provides nationwide home delivery of medical products and medications, as well as wellness and chronic condition management solutions to beneficiaries, and health care business process outsourcing and member service to insurers offering Medicare and other insurance coverage.

¹ Collectively, the Patient Protection and Affordable Care Act (P.L. 111-148), as amended by the Health Care and Education Reconciliation Act of 2010 (P.L. 111-152).

² Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations, Final rule, 76 FR 67802, Nov. 2, 2011 (codified at 42 C.F.R. Part 425, Medicare Shared Savings Program). For a complete review and analysis of these regulations see, The Controversial Draft Medicare ACO Regulations: Analysis, Comments and Recommended Action, <http://www.mwe.com/publications/uniEntity.aspx?xpST=PublicationDetail&pub=6664> and Medicare Shared Savings Program Final Rule: Where Do We Go from Here?, <http://www.mwe.com/info/news/wp1211a.pdf>.

³ For more detail, see the Institute for Healthcare Improvement Triple Aim Initiative, <http://www.ihl.org/offerings/Initiatives/TripleAim/Pages/default.aspx>.

⁴ Final rule, 76 FR 67802, 67804, Nov. 2, 2011.

MSSP, and discusses in further detail the program integrity requirements designed to protect the program from fraud and abuse, as well as the contrasting flexibility provided by certain waivers of otherwise applicable fraud and abuse laws.

¶25,505 An Overview of the MSSP

The Medicare Shared Savings Program (MSSP) is intended to promote accountability for a patient population, coordinate items and services under Medicare Parts A and B, and encourage investment in infrastructure and redesigned care processes for high-quality and efficient service delivery. An accountable care organization (ACO) that meets the MSSP's eligibility requirements and quality performance standards is eligible to receive a share of the savings it generates.

Governance and Legal Structure

To be eligible to participate in the MSSP, an ACO, among other things, must establish a formal legal structure and mechanism for shared governance that allows for the receipt and distribution of shared savings among one or more of the following types of providers:⁵

- ACO professionals⁶ in group practice arrangements,
- networks of individual practices of ACO professionals,
- partnerships or joint venture arrangements between hospitals and ACO professionals,
- hospitals⁷ employing ACO professionals,
- critical access hospitals (CAHs) that bill under Method II,
- federally qualified health centers (FQHCs),
- rural health clinics (RHCs).

Other entities are eligible to participate in the MSSP through an ACO formed by one of the above types of providers, but they may not form their own ACO independently and participate in the MSSP.⁸

An ACO must be a legal entity, formed under applicable state, federal, or tribal law, that is authorized to conduct business in each state in which it operates for purposes of (i) receiving and distributing shared savings; (ii) repaying shared losses or other monies determined to be owed to CMS; (iii) establishing, reporting, and ensuring provider compliance with health care quality criteria, including quality performance standards; and (iv) fulfilling other ACO functions. An ACO formed by two or more otherwise independent participants must be a legal entity separate from any of its participants.⁹ Further, an ACO must have a mechanism for shared governance.¹⁰ The governing body must have authority to execute the functions of the ACO, including, but not limited to, processes to promote evidence-based medicine and patient engagement, report on quality and cost measures, and coordinate care.¹¹

With respect to leadership and management structure, an ACO must have clinical and administrative systems capable of the following:

- Promoting evidence-based medicine and patient engagement; reporting on quality and cost measures; and coordinating care, such as through the use of telehealth, remote patient monitoring, and other such enabling technologies.¹²
- Demonstrating compliance with the patient-centeredness criteria, such as the use of patient and caregiver assessments or the use of individualized care plans.¹³

Finally, the ACO's operations must be managed by an executive, officer, manager, or general partner whose appointment and removal are under the con-

⁵ Medicare Shared Savings Program, 42 C.F.R. §425.102(a) (2012).

⁶ CMS defines an "ACO professional" as an ACO provider/supplier who is either (1) a physician legally authorized to practice medicine and surgery by the state in which he or she performs such function or action, or (2) a practitioner who is one of the following: (i) a physician assistant (as defined at 42 C.F.R. §410.74(a)(2)); (ii) a nurse practitioner (as defined at §410.75(b)); or (iii) a clinical nurse specialist (as defined at §410.76(b)). See 42 C.F.R. §425.20.

⁷ "Hospital" means an acute care hospital subject to the prospective payment system as specified at 42 C.F.R. §412.1(a)(1).

⁸ 42 C.F.R. §425.102(b).

⁹ 42 C.F.R. §425.104(b).

¹⁰ Social Security Act §1899(b)(1).

¹¹ 42 C.F.R. §425.106(a).

¹² Social Security Act §1899(b)(2)(G); see also Final rule, 76 FR 67802, 67826 – 67830, Nov. 2, 2011 (codified at 42 C.F.R. Part 425).

¹³ Social Security Act §1899(b)(2)(H).

trol of the organization's governing body and whose leadership team has demonstrated the ability to influence or direct clinical practice to improve efficiency, processes, and outcomes.¹⁴ Clinical management and oversight must be administered by a senior-level medical director who is board-certified, one of the ACO's participating physicians, and physically present on a regular basis at a clinic, office, or other facility within the ACO network.¹⁵

Agreement with CMS

An ACO must enter into a written agreement with CMS for a period of at least three years.¹⁶ As discussed under Beneficiary Assignment, although beneficiaries have the freedom to choose (and change) their physicians who might participate in an ACO,¹⁷ the MSSP implicitly assumes that a majority of assigned beneficiaries will remain within the ACO during the applicable contract period, thus affording the ACO an opportunity to improve the quality, experience of care, and cost of caring for such individuals not only with respect to isolated episodes of care, but also over an extended period of time.

Beneficiary Assignment

ACOs participating in the MSSP must agree to be accountable for the quality, cost, and overall care of not fewer than 5,000 Medicare FFS beneficiaries assigned to it.¹⁸ CMS will assign Medicare beneficiaries to an ACO based on their selection of primary care service providers¹⁹ from whom they receive the plurality of their primary care services. There is no proactive action that beneficiaries must take to be assigned to an ACO, and once a beneficiary is assigned to an ACO, he or she cannot opt out of such assignment except by seeking primary care services from another provider.²⁰ There is no mechanism for an ACO to solicit assignment of certain beneficiaries or reject individual beneficiaries from the ACO. ACOs are precluded from appealing determination

of beneficiaries assigned by CMS.²¹ The ACO assignment process is not akin to "enrollment" in an ACO. Beneficiaries retain the freedom of choice to see any provider they choose, regardless of whether or not the provider is associated with the ACO to which he or she is assigned.²² An ACO is prohibited from avoiding at-risk patients to minimize costs to the ACO. If CMS identifies trends and patterns suggesting that an ACO has avoided at-risk beneficiaries and after further investigation substantiates cases of beneficiary avoidance, CMS may impose sanctions against the ACO, including termination from the Medicare program.²³

Quality Standards

Quality is a cornerstone of the MSSP. Providers participating in the MSSP through an ACO will continue to be paid in accordance with payments they receive under the original Medicare FFS program and will be eligible to receive a "shared savings" payment if, in addition to demonstrating savings in expenditures for both Medicare Part A and Part B services, the ACO meets quality performance standards established by CMS.²⁴

CMS will measure and assess quality performance through the following:

- clinical processes and outcomes,
- patient and, when practicable, caregiver experience of care, and
- utilization (such as rates of hospital admissions for ambulatory care sensitive conditions).²⁵

More specifically, CMS has established 33 quality performance standard measures in four areas ("domains"):

- patient/caregiver experience,
- care coordination,
- preventive health, and
- at-risk population/frail elderly health.²⁶

¹⁴ 42 C.F.R. § 425.108(b).

¹⁵ 42 C.F.R. § 425.108(c).

¹⁶ 42 C.F.R. § 425.200(a).

¹⁷ 42 C.F.R. § 425.400(b).

¹⁸ 42 C.F.R. § 425.110.

¹⁹ 42 C.F.R. § 424.400.

²⁰ Beneficiaries may, however, opt out of data-sharing between CMS and the ACO. See 42 C.F.R. § 425.708.

²¹ 42 C.F.R. § 425.800(a)(3).

²² 42 C.F.R. § 425.400(b); Final rule, 76 FR 67802, 67851, 67866, Nov. 2, 2011 (codified at 42 C.F.R. Part 425).

²³ 42 C.F.R. § 425.316(b). See 42 C.F.R. § 425.216(a)(1).

²⁴ See generally 42 C.F.R. 425 Subpart F.

²⁵ Social Security Act § 1899(b)(3)(A).

²⁶ See Final rule, 76 FR 67802, 67889, 67890, Nov 2, 2011.

For an ACO to satisfy performance measures in any of these domains, the ACO must report all measures within that domain, and score above the minimum attainment level determined by CMS on 70 percent of the measures in each domain.²⁷

Each ACO will be required to submit data that allows CMS to evaluate the quality of care furnished by the ACO and assess an ACO's success in promoting the aims of better care for individuals, better health for populations, and lower growth in expenditures.²⁸ Such data is closely linked to information reported through other measures, such as through the Physician Quality Reporting System (PQRS) or Consumer Assessment of Health Care Providers and Systems (CAHPS) surveys, and include performance measures such as:

- patients getting timely care, appointments, and information;
- health promotion and education;
- reporting on certain immunizations; and
- disease specific information related to diabetes, hypertension, ischemic vascular disease, heart failure, and coronary artery disease.

CMS will evaluate the data reported by ACOs against the various 33 quality performance measures and will expect ACOs to improve, on a continuous basis, the quality of care provided to Medicare beneficiaries receiving care through the ACOs.

Shared Savings

The underlying principle of the MSSP is that care coordination together with an improvement in quality will result in a reduction in health care expenditures. ACOs that are effective in reducing health care expenditures by improving quality are eligible to receive a portion of any shared savings. Eligibility for any shared savings will be dependent on whether the "estimated average per capita Medicare expenditures" under the ACO for Medicare fee-for-service beneficiaries for Part A and Part B services,

adjusted for beneficiary characteristics, is at least a specified percent specified by CMS below the applicable benchmark.²⁹ If the ACO meets the quality performance standards noted above, the ACO may be paid a percent of the difference between (i) the average per capita Medicare expenditures in a year, adjusted for beneficiary characteristics, under the ACO and (ii) such benchmark established for the ACO.

For the purpose of developing the benchmark against which Medicare expenditures for an ACO's assigned patients will be compared, CMS will use the spending data from Medicare beneficiaries that would have been assigned to the ACO in the most recent available three-year historical period (adjusted for beneficiary characteristics).³⁰ The benchmark can be adjusted in three ways. First, it can be adjusted for an ACO desiring to add or remove participants during the agreement period.³¹ Second, the benchmark is adjusted annually based on the projected absolute amount of growth in national per capita Medicare expenditures.³² Third, an ACO's benchmark is reset at the beginning of each agreement period so that an ACO renewing its agreement will have its benchmark determined by the most recent actual, as opposed to projected, data.³³

There are two MSSP shared savings models. The first is a one-sided ACO model, referred to as Track 1, under which the ACO is eligible to share up to 50 percent of any Medicare savings.³⁴ The second is the two-sided model, referred to as Track 2, under which the ACO is eligible to share up to 60 percent of any Medicare shared savings below its benchmark or is required to repay certain amounts expended by CMS above the ACO's benchmark.³⁵ To share in savings under both Track 1 and Track 2, an ACO's average per capita Medicare expenditures must be below CMS-established benchmark amounts by at least the "minimum savings rate."³⁶ The percentage of shared savings that an ACO will receive will vary

²⁷ 42 C.F.R. § 425.502(d)(2).

²⁸ 42 C.F.R. § 425.500(b)(1), (c).

²⁹ 42 C.F.R. §§ 425.604(a), 425.606(a).

³⁰ 42 C.F.R. § 425.602.

³¹ 42 C.F.R. § 425.602(a)(8).

³² 42 C.F.R. § 425.602(b).

³³ 42 C.F.R. § 425.602(c).

³⁴ 42 C.F.R. § 425.604(d). After the initial agreement period, all ACOs must participate in a two-sided model if they wish to continue to participate in the MSSP.

³⁵ 42 C.F.R. § 425.606(d).

³⁶ 42 C.F.R. §§ 425.604, 425.606.

based on how well it scores on its quality measures.³⁷ The shared savings payment is subject to a cap.³⁸

CMS Discretion

CMS will have sole and ultimate authority (*i.e.*, not subject to judicial review) over the following:

- establishment of the quality performance standards and assessment of the ACO's performance against such standards;³⁹
- assignment of Medicare FFS beneficiaries to the ACO;⁴⁰
- determination of (i) whether an ACO is eligible for shared savings and the amount of such shared savings, including the determination of the estimated average per capita Medicare expenditures under the ACO for Medicare FFS beneficiaries assigned to the ACO and the average benchmark for the ACO, (ii) the percent of shared savings, and (iii) any limit on the total amount of shared savings;⁴¹
- termination of an ACO from the MSSP.⁴²

¶25,510 Compliance Concerns for ACOs

Involvement in any government program inherently incorporates a number of rules and requirements with which a participating entity must comply; participation in the Medicare Shared Savings Program (MSSP) is no exception. In addition to the general program requirements, several fundamental aspects of the MSSP require accountable care organizations (ACOs) to dedicate adequate attention and resources to ensure program compliance, particularly (i) the MSSP's compliance plan requirements, (ii) agreements between an ACO and its participants or its providers and suppliers, (iii) determination of conflicts of interest within the ACO governing body, and (iv) prohibition against ACO beneficiary inducements.

Compliance Plan Requirements

The Patient Protection and Affordable Care Act (PPACA) (P.L. 111-148) and CMS require ACOs to

adopt a compliance plan that includes at least five of the seven elements common in the industry, generally stemming from the U.S. Federal Sentencing Guidelines, including:

- a designated compliance official or individual who is not legal counsel to the ACO and who reports directly to the ACO's governing body,
- mechanisms for identifying and addressing compliance problems related to the ACO's operations and performance,
- a method for employees or contractors of the ACO or ACO providers/suppliers to report suspected problems related to the ACO,
- compliance training of the ACO's employees and contractors, and
- a requirement to report suspected violations of law to an appropriate law enforcement agency.⁴³

Organizations that participate in the MSSP may have compliance programs in place, and CMS has indicated that there is no need to duplicate efforts to the extent the existing compliance program satisfies these requirements, so long as the ACO can demonstrate that its compliance mechanisms are "effective."⁴⁴ ACOs wishing to use an existing compliance program, however, should evaluate whether it meets the specific needs for participation in the MSSP before adopting such plan on behalf of the ACO. In addition, ACOs should be prepared to demonstrate the "effectiveness" of its compliance program, such as through detailed policies and procedures designed to monitor and evaluate how well or poorly the compliance plan identifies and resolves risks.

CMS took some time to discuss the role of the Compliance Officer in the final rule implementing the MSSP. In particular, CMS clarified that while the compliance officer cannot also serve as legal counsel to the organization, it did not mean to imply that an attorney could not serve as the compliance officer.⁴⁵ CMS believes that the separation of the compliance officer and legal counsel "ensure[s] independent and

³⁷ 42 C.F.R. §§ 425.604(d), 425.606(d).

³⁸ 42 C.F.R. §§ 425.604(e)(2), 425.606(e)(2).

³⁹ 42 C.F.R. § 425.800(a)(1)–(2).

⁴⁰ 42 C.F.R. § 425.800(a)(3).

⁴¹ 42 C.F.R. § 425.800(a)(4)–(5).

⁴² 42 C.F.R. § 425.800(a)(6).

⁴³ 42 C.F.R. § 425.300(a).

⁴⁴ See Proposed rule, 76 FR 19528, 19552 April 7, 2011 (to be codified at 42 C.F.R. Part 425).

⁴⁵ Final rule, 76 FR 67802, 67952, Nov. 2, 2011 (codified at 42 C.F.R. Part 425).

objective legal reviews and financial analyses of the organization's compliance efforts and activities by the compliance officer."⁴⁶ In addition, although existing organizations can use their current compliance officer to satisfy this program integrity requirement, that compliance officer cannot serve as legal counsel to the existing organization.⁴⁷

Agreements between ACOs and ACO Participants and between ACOs and ACO Providers/Suppliers

CMS emphasizes that each ACO maintains ultimate responsibility for compliance with all terms and conditions of its MSSP agreement.⁴⁸ To ensure that the all entities that participate in an ACO remain committed to comply with the MSSP requirements, all contracts between an ACO, its ACO participants and ACO providers and suppliers (or other entities furnishing services related to ACO activities) must mandate that the contracting entities comply with the ACO program requirements.⁴⁹ Further, CMS will require an authorized representative of the ACO with authority to legally bind the ACO to certify to the accuracy, completeness, and truthfulness of (1) application of the MSSP to the ACO, (2) the ACO's agreement with CMS, and (3) quality and other data submitted by the ACO to CMS. Similarly, each written request for a shared savings payment must include a certification from an authorized representative of the ACO that the ACO is in compliance with program requirements, as well as to the accuracy, completeness, and truthfulness of any information submitted directly or indirectly by the ACO.

Conflicts of Interest

An ACO must have a conflicts of interest policy in place applicable to members of the ACO's governing body requiring such members disclosure of relevant financial interests so that the ACO may determine whether a conflict exists.⁵⁰ The policy also must include remedial actions concerning members of the

governing body who fail to comply with this requirement.⁵¹ CMS, however, does not define what is meant by a "relevant financial interest," which could lead to a number of uncertainties when evaluating whether a conflict, perceived or real, would prevent an entity from participating in an ACO.

Prohibition Against Beneficiary Inducements

There is an intrinsic tension between the PPACA's requirement that an ACO establish "processes to promote . . . patient engagement,"⁵² and ways in which ACOs can promote such engagement absent implicating federal fraud and abuse laws. To address this tension, CMS attempted to establish several "bright line" rules that prohibit beneficiary inducements. The ACO and its participants, providers/suppliers, and others performing services or other functions for the ACO are "prohibited from providing gifts, cash, or other remuneration for receiving services from or remaining in an ACO or with a particular provider within the ACO."⁵³ Notwithstanding those prohibitions, ACOs may offer, consistent with other applicable laws, "in-kind items or services to beneficiaries if there is a reasonable connection between the items and services and the medical care of the beneficiary and the items or services are preventive care items or services or advance a clinical goal for the beneficiary."⁵⁴

More specifically, the item or service must advance one or more of the following clinical goals:

- adherence to a treatment regime,
- adherence to a drug regime,
- adherence to a follow-up care plan, and
- management of a chronic disease or condition.⁵⁵

An example of an item that might have a reasonable connection to the medical care of the beneficiary is a blood pressure monitor given to a patient with hypertension to encourage regular blood pressure monitoring, and, thus, "engage[ing] beneficiaries to be more proactive in their disease management."⁵⁶

⁴⁶ Id.

⁴⁷ Id.

⁴⁸ 42 C.F.R. § 425.314(c).

⁴⁹ Final rule, 76 FR 67802, 67953, Nov. 2, 2011.

⁵⁰ 42 C.F.R. § 425.106(d).

⁵¹ 42 C.F.R. § 425.106(d)(3).

⁵² Social Security Act § 1899(b)(2)(G).

⁵³ 42 C.F.R. § 425.304(a)(1).

⁵⁴ 42 C.F.R. § 425.304(a)(2).

⁵⁵ Final rule, 76 FR 67802, 67958, Nov. 2, 2011 (codified at 42 C.F.R. Part 425).

⁵⁶ Id.

Conversely, baseball tickets, jewelry, household items, and gift certificates for nonhealth care related items generally do not have a “reasonable connection” to the medical care of the beneficiary.⁵⁷ While there are some very clear-cut lines between what is permissible (*e.g.*, blood pressure monitor) and what is prohibited (*e.g.*, baseball tickets), there are some items for which it may be less obvious whether or not it is permissible under these guidelines. Therefore, ACOs must carefully consider any proposed item or service offered to patients designed to promote patient engagement and ensure that it is “reasonably connected” to the medical care of the beneficiary so as not to run afoul of CMS’s prohibition against beneficiary inducements.

¶ 25,515 CMS’s Monitoring Activities

In addition to general compliance concerns, CMS has indicated that it will monitor five specific areas of accountable care organization (ACO) operations:

- avoidance of at-risk beneficiaries,⁵⁸
- compliance with performance standards,⁵⁹
- meeting eligibility requirements,⁶⁰
- beneficiary notification of ACO participation and ability to opt-out of data sharing,⁶¹ and
- marketing materials and activities.⁶²

ACOs should pay special attention to these areas to ensure that their operations satisfy CMS’ expectations and requirements.

CMS will monitor and assess the performance of an ACO, its participants, and its providers and suppliers through the following methods (and may use other methods or resources as appropriate):

- analysis of the ACO’s reported financial and quality measurement data, as well as its aggregate annual and quarterly reports;⁶³
- analysis of complaints made by the ACO’s beneficiaries and providers;⁶⁴ and

- audits of ACO operations (including, for example, analysis of claims, medical record reviews, beneficiary survey reviews, coding audits, on-site compliance reviews).⁶⁵

Avoidance of At-Risk Beneficiaries

CMS will take specific steps if its monitoring identifies deficiencies in compliance with requirements to enroll at-risk beneficiaries and quality performance standards. If CMS identifies that an ACO exhibits trends or patterns that suggest it is avoiding at-risk beneficiaries, CMS may require the ACO to submit a corrective action plan (CAP).

An “at-risk beneficiary” means (but is not limited to) a beneficiary who:

- has a high risk score on the CMS-HCC risk adjustment model,
- is considered high cost due to having two or more hospitalizations or emergency room visits each year,
- is dually eligible for Medicare and Medicaid,
- has a high utilization pattern,
- has one or more chronic conditions,
- has had a recent diagnosis that is expected to result in increased cost,
- is entitled to Medicaid because of disability, or
- is diagnosed with a mental health or substance abuse disorder.⁶⁶

CMS will identify ACOs that could be avoiding at-risk beneficiaries by:⁶⁷

- Analyzing claims and examining other beneficiary-level documentation to identify trends and patterns suggestive of avoidance of at-risk beneficiaries. Examples of beneficiary-level documentation that may be reviewed include beneficiary satisfaction surveys and medical record audits. CMS also may review changes in

⁵⁷ Id.

⁵⁸ 42 C.F.R. § 425.316(b).

⁵⁹ 42 C.F.R. § 425.316(c).

⁶⁰ Proposed rule, 76 FR 19528, 19626, April 7, 2011 (to be codified at 42 C.F.R. Part 425); See also 42 C.F.R. § 425.218(b), granting CMS the authority to terminate an ACO that is not compliant with eligibility requirements.

⁶¹ See 42 C.F.R. § 425.310(d), establishing sanctions for failing to comply with the MSSP marketing requirements.

⁶² Id.

⁶³ 42 C.F.R. § 425.316(a)(2)(i).

⁶⁴ 42 C.F.R. § 425.316(a)(2)(ii).

⁶⁵ 42 C.F.R. § 425.316(a)(2)(iii).

⁶⁶ 42 C.F.R. § 425.20.

⁶⁷ Final rule, 76 FR 67802, 67951, Nov. 2, 2011.

risk adjustment of beneficiaries assigned to an ACO in the prior year who are not assigned in the current performance year to help determine whether there is a pattern of avoidance.

- Collecting, evaluating, and investigating beneficiary and provider complaints to identify ACOs that might be attempting to avoid at-risk beneficiaries.

The results of the above analyses could lead CMS to further investigate the ACO and follow-up with beneficiaries or the ACO itself for more information. CMS may reach out to any of the ACO's participants, providers or suppliers, as well as individuals or entities performing ACO activity-related services or functions. If the ACO exhibits a pattern of avoidance, CMS may determine an audit of the ACO is necessary. Upon a finding that an ACO has been avoiding at-risk beneficiaries during a performance year, the ACO will be notified and required to submit a CAP to CMS for approval. An ACO operating under a CAP as a result of CMS determining that the ACO avoided at-risk beneficiaries is prohibited from receiving shared savings payments while under the CAP regardless of the performance period in question and is ineligible to earn any shared savings for the period during which it is under the CAP. CMS will reevaluate an ACO operating under a CAP both during and at the end of the CAP. If CMS determines that the ACO has continued to avoid at-risk beneficiaries while operating under the CAP, CMS will terminate the ACO from the Medicare Shared Savings Program (MSSP), and may make such termination effective immediately.

Compliance with Performance Standards

In addition to the corrective actions and termination provisions, CMS may take additional compliance enforcement steps for ACOs that fail to meet quality performance requirements.⁶⁸ ACOs that do not achieve the minimum attainment level in one or more quality reporting domains would have one year to improve performance before being subject to a CAP or termination. Alternatively, ACOs meeting

this characteristic that failed to report a measure or provided incomplete or inaccurate data would be given an opportunity to resubmit and/or provide a written explanation for the reporting deficiencies. ACOs that demonstrate a pattern of quality reporting deficiencies, however, could be sanctioned or terminated from the MSSP.⁶⁹

CMS will review ACOs' submissions of quality measurement data to identify ACOs that are not meeting the quality performance standards.⁷⁰ CMS also may request additional documentation from an ACO, its participants or its providers/suppliers, as appropriate.⁷¹ If an ACO does not meet quality performance standards, CMS will:

- Provide a warning notice to the ACO regarding noncompliance with one or more program requirements. The ACO may be given a warning for the first time it fails to meet the minimum attainment level in one or more domains.⁷²
- Request a CAP from the ACO and place the ACO on a special monitoring plan. The ACO's performance will be monitored and evaluated by CMS during and after the CAP process.⁷³
- Re-evaluate the ACO's compliance with the quality performance standards the following year. If CMS finds that the ACO continues to fail to meet quality performance standards in the following year, it will terminate the ACO's agreement.⁷⁴

Depending on the nature and severity of the non-compliance, CMS may forgo the issuance of the warning letter and, instead, subject the ACO to notice of noncompliance and request for CAP and other processes, or immediately terminate the ACO's agreement.⁷⁵

When an ACO fails to report one or more quality measures or fails to report completely and accurately on all measures in a domain, CMS will request that the ACO submit the required measure data, correct the inaccurate data, provide a written explanation for why it did not report the data completely and accurately, or any combination of these require-

⁶⁸ 42 C.F.R. § 425.316(c).

⁶⁹ 42 C.F.R. § 425.500(f).

⁷⁰ 42 C.F.R. § 425.316(c).

⁷¹ Id.

⁷² 42 C.F.R. § 425.316(c)(1).

⁷³ Id.

⁷⁴ 42 C.F.R. § 425.316(c)(2).

⁷⁵ Final rule, 76 FR 67802, 67951, Nov. 2, 2011.

ments.⁷⁶ An ACO that fails to (1) report the requested data, (2) report by the requested deadline, or (3) provide a reasonable explanation for not reporting will be subject to immediate termination.⁷⁷ If an ACO fails to make timely corrections following receipt of notice from CMS to resubmit its report, CMS may terminate the ACO from the MSSP.⁷⁸ An ACO that fails to report fully and completely on quality performance measures will be prevented from qualifying to share in savings earned during that reporting year.⁷⁹

Eligibility Requirements

CMS also will monitor ACOs for continued maintenance of eligibility requirements to participate in the MSSP.⁸⁰ In addition, CMS will look for any material change impacting an ACO's ability to meet eligibility requirements, including (but not limited to):

- changes in ACO participants that are the basis for beneficiary assignment to the ACO;
- increase in ACO provider/supplier composition that results in a reviewing antitrust agency stating it is likely to challenge, or recommend challenging, the ACO;
- changes in the ACO's leadership and management structure, resulting in the ACO's inability to perform eligibility or governance functions required for its participation in the MSSP;
- sanctions or other actions taken against the ACO, its ACO participants, its ACO providers/suppliers, or contracted entities performing services or functions on behalf of the ACO by an accrediting organization or by a state, federal, or local government agency.⁸¹

The final rule implementing the MSSP also specifically states that CMS will use various monitoring methods, such as quarterly aggregated reports, to determine whether an ACO continues to meet the required 5,000 beneficiary threshold during the

course of its contract.⁸² While these are just a few ways CMS has explicitly stated that it will monitor ACOs for maintenance of eligibility requirements, CMS may monitor ACOs for any requirements necessary for an ACO to participate in the MSSP.

Data Sharing and Beneficiary Opt-Out

Perhaps not the first issue to come to mind when considering compliance obligations under the MSSP, noncompliance with the MSSP's data sharing requirements could present considerable risk to ACOs. Significant amounts of beneficiary data will need to be shared with the ACO and used to achieve the Triple Aim objectives (see ¶ 25,500).⁸³ CMS has recognized, however, its belief that "beneficiaries should be notified of, and have control over, who has access to their personal health information (PHI)" for purposes of the MSSP.⁸⁴ Thus, ACOs are subject to certain limitations and conditions on the sharing of the CMS beneficiary-identifiable claims data, and specific disclosure prohibitions and restrictions imposed under applicable federal law.

First, before requesting claims data about a particular patient, the ACO must notify the patient that it may request PHI about the beneficiary for purposes related to its participation in the MSSP.⁸⁵ This notice must provide the patient with the opportunity to decline having his or her claims information shared with the ACO. Second, ACOs may contact preliminary prospective assigned beneficiaries in writing to request data sharing. Such beneficiaries are deemed to have consented to their information being shared with the ACO if they do not decline within 30 days after the letter is sent.⁸⁶ Finally, as part of its overall communication, the ACO must provide beneficiaries with a standardized written notice at the time they seek services from one of the ACO's primary care physicians of its participation in the MSSP and the potential for CMS to share the patient's identifiable data with the ACO. The written notice must provide

⁷⁶ 42 C.F.R. § 425.316(c)(3)(i).

⁷⁷ 42 C.F.R. § 425.316(c)(3)(ii).

⁷⁸ 42 C.F.R. § 425.316(c)(4).

⁷⁹ 42 C.F.R. § 425.316(c)(5).

⁸⁰ 42 C.F.R. § 425.218(b)(1).

⁸¹ Proposed rule, 76 FR 19528, 19626, April 7, 2011 (to be codified at 42 C.F.R. Part 425).

⁸² Final rule, 76 FR 67802, 67959, Nov. 2, 2011.

⁸³ "Triple Aim" objectives consist of (1) better care for individuals, (2) better health for populations, and (3) lower growth in expenditures. The MSSP will reward ACOs that lower growth in health care costs and meet performance standards on quality of care.

⁸⁴ Final rule, 76 FR 67802, 67849, Nov. 2, 2011.

⁸⁵ 42 C.F.R. § 425.708(a).

⁸⁶ 42 C.F.R. § 425.708(b).

beneficiaries with notice of their opportunity to opt out of having their CMS claims data shared with the ACO.⁸⁷ If a beneficiary declines to have his or her data shared through any of these mechanisms, the ACO may not request his or her data. CMS will maintain a list of health insurance claim numbers (HICNs)⁸⁸ that have elected to opt out.

ACOs must prepare signage and written notices to explain to beneficiaries the possibility that CMS may share their identifiable information with the ACO as well as a form that a beneficiary can use to exercise his or her information-sharing opt-out right. To be meaningful, an opportunity to opt out must:

- be provided with enough advance notice for the beneficiary to make the opt-out decision,
- provide adequate information about how the information will be shared and used by the ACO and the benefits and risks of the beneficiary in making his or her data available for the proposed uses,
- not be coercive, and
- not permit the information to be used for discriminatory purposes.

ACOs should bear in mind that these signs and written notices are subject to CMS's marketing requirements⁸⁹ and must be approved through CMS' marketing approval process. In addition, ACOs should consider maintaining a list of those patients who have opted-out of data sharing so that improper requests are not inadvertently made. Lastly, ACOs should adopt policies to ensure that patients who have opted out are not somehow coerced into data-sharing or are otherwise discriminated against.

Marketing Requirements

In line with its patient-centeredness focus, CMS highlights its concern that beneficiaries may be misled about the benefits of and services available from an ACO. To protect against that type of conduct, all

ACO marketing materials, communications, and activities related to the ACO and its participation in the MSSP (and any changes to these materials) are subject to CMS approval, similar to those requirements that govern marketing materials under Medicare Advantage and Medicare Part D.⁹⁰ Organizations that previously have not been required to submit marketing materials to CMS for approval might have to adjust some of their processes. If the Medicare Advantage and Medicare Part D marketing guidelines are any indication, the marketing guidelines governing ACOs will contain some very specific requirements, such as permissible font sizes, footnote placement, and required disclosures. ACOs will have to build in lead time into the development of these materials to allow for CMS' approval and be prepared to make revisions if necessary.

CMS defines "marketing materials" to include: general audience materials such as brochures, advertisements, outreach events, letters to beneficiaries, web pages, data sharing opt-out letters, mailings, social media, or other activities, and includes any materials or activities used by ACO participants or ACO providers/suppliers on behalf of the ACO.⁹¹ Informational materials, non-ACO related pieces, referrals, billing/claims communications, and medical condition-related mailings (e.g., flu shots), however, are not marketing materials subject to approval by CMS. ACOs that fail to adhere to CMS's marketing guidelines may be placed under a CAP and may be subject to sanctions or termination from the MSSP at CMS's discretion.⁹²

¶ 25,520 Implication of Fraud and Abuse Laws, Waivers

Concurrently with the release of the final rule implementing the Medicare Shared Savings Program (MSSP),⁹³ CMS and the Office of Inspector General, Department of Health and Human Services (OIG)

⁸⁷ 42 C.F.R. § 425.708(c).

⁸⁸ The health insurance claim number (HICN) refers to the number assigned by the Social Security Administration to an individual for the purpose of identifying him or her as a Medicare beneficiary. The HICN is comprised of two parts namely the claim account number (CAN) and the beneficiary identification code number (BIC). CAN is the policy number of the wage owner who earns Medicare benefits and BIC identifies the current relationship between wage earner and beneficiary.

⁸⁹ See text accompanying note 71 (data sharing opt-out letters are included in CMS' definition of "marketing materials" and, therefore, are held to same requirements).

⁹⁰ 42 C.F.R. § 425.310.

⁹¹ 42 C.F.R. § 425.20.

⁹² 42 C.F.R. § 425.310(d).

⁹³ Final rule, 76 FR 67802, Nov. 2, 2011 (codified at 42 C.F.R. Part 425).

(collectively, the Agencies) issued an interim final rule with comment period (the Final ACO Waivers Rule) setting forth the scope, terms, and conditions of waivers of four federal laws that would otherwise prohibit or impede the development and operation of accountable care organizations (ACOs) wishing to participate in the MSSP.⁹⁴ Specifically, the Final ACO Waivers Rule addresses:

- the federal physician self-referral law (commonly known as the Stark law),⁹⁵
- the federal anti-kickback statute (the Anti-Kickback Law),⁹⁶
- the provisions of the civil monetary penalties law prohibiting hospital payments to a physician to induce the physician to reduce or limit care to a Medicare or Medicaid beneficiary under the physician's direct care (the Gainsharing CMP),⁹⁷ and
- the provisions of the civil monetary penalties law prohibiting inducements to a Medicare or Medicaid beneficiary likely to influence the beneficiary's choice of a provider, practitioner, or supplier (the Beneficiary Inducements CMP).⁹⁸

The Final ACO Waivers Rule includes the five waivers discussed below that protect ACOs and their relationships from liability under these laws.

Pre-participation Waiver

The pre-participation waiver⁹⁹ allows an ACO participant or ACO provider/supplier (*e.g.*, a hospital) to furnish or fund ACO development services for the economic benefit of all of the ACO's participants, including referring physicians, without risk of liability under the Stark Law, the Anti-Kickback Law or the Gainsharing CMP Law (collectively the fraud and abuse laws) if procedural requirements are met.

Arrangements to furnish or fund ACO development services with drug and device manufacturers, distributors, durable medical equipment suppliers, or home health agencies are not protected from compliance with the fraud and abuse laws by this waiver.

Also, if the start-up arrangements include continual financial arrangements with referral sources, contracts with such referral sources must contain "out" or "unwind" provisions. Documentation related to relationships covered by this waiver must be (i) retained by the ACO and, by implication, any party that may need the protection of this waiver, for 10 years; (ii) be prepared contemporaneously with the transaction; and (iii) made available to CMS upon request.

Waiver protection begins one year preceding the application due date for the ACO's starting year, (unless the starting year is 2012, in which case the waiver protects start-up arrangements occurring on and after November 2, 2011). The pre-participation waiver may be used only once by an ACO. The waiver ends on the earlier of the MSSP participation agreement start date (application accepted), six months after the date of CMS's application denial notice (application denied), or the earlier of application due date or date of ACO's explanatory statement to CMS (application not filed). Further, an ACO's governing body must make a *bona fide* determination that the arrangement is reasonably related to the purposes of the MSSP and the ACO must demonstrate a likelihood of successfully participating in the MSSP by the next available application due date. For purposes of the waiver, the "Purposes of the Shared Savings Program" means the aims of: (i) promoting accountability for the quality, cost, and overall management for a Medicare patient population; (ii) managing and coordinating care for Medicare fee-for-service beneficiaries through an ACO; and (iii) encouraging investment in infrastructure and redesigned care processes for high quality and efficient service delivery for patients.

Participation Waiver

The participation waiver¹⁰⁰ protects all of the parties to an arrangement continuing or commencing on and after an ACO enters into a MSSP participation agreement without risk of liability under the Stark

⁹⁴ Interim final rule with comment period, 76 FR 67992, Nov. 2, 2011. The comment period closed January 3, 2012. CMS and OIG must consider any comments submitted by that time and publish a final rule addressing those comments within three years.

⁹⁵ 42 U.S.C. § 1395nn (2011).

⁹⁶ 42 U.S.C. § 1320a-7b(b).

⁹⁷ 42 U.S.C. § 1320a-7a(b)(1) and (2).

⁹⁸ 42 U.S.C. § 1320a-7a(a)(5).

⁹⁹ Interim final rule with comment period, 76 FR 67992, 68,000, Nov. 2, 2011.

¹⁰⁰ *Id.*

Basics of the Law

Law, the Anti-Kickback Law and the Gainsharing CMP Law if certain procedural requirements are met:

- the arrangements must involve an ACO, an ACO participant, or an ACO provider/supplier;
- financial arrangements must have “out” or “unwind” provisions;
- documentation reflecting waived relationships must be (i) retained by the ACO and, by implication, any party that may need the protection of this waiver, for 10 years; (ii) prepared contemporaneously with the transaction; and (iii) made available to CMS upon request.

As with the pre-participation waiver, the ACO’s governing body must make a *bona fide* determination that the arrangement is reasonably related to the purposes of the MSSP, which are: (i) promoting accountability for the quality, cost, and overall management for a Medicare patient population; (ii) managing and coordinating care for Medicare fee-for-service beneficiaries through an ACO; and (iii) encouraging investment in infrastructure and redesigned care processes for high quality and efficient service delivery for patients.

If these requirements are met, waiver protection begins upon implementation of participation in the MSSP and ends either (i) six months following the expiration of the participation agreement and any renewals, or (ii) contemporaneous with either the date on which the ACO voluntarily terminates its participation in the MSSP, or the date of the CMS MSSP termination notice.

Stark Law Waiver

Under the Stark Law Waiver,¹⁰¹ the Anti-Kickback Law and the Gainsharing CMP are waived with respect to any financial relationship between or among the ACO, its ACO participants, and its ACO providers/suppliers that implicates the Stark Law,¹⁰² provided that all of the following requirements are met:

- the ACO has entered into a participation agreement under the MSSP and remains in good standing under such agreement;
- the financial relationship is reasonably related to the purposes of the Shared Savings Program (defined above);
- the financial relationship fully complies with one of the Stark Law’s designated health services (DHS), ownership/investment, or compensation exceptions (42 C.F.R. §§411.355 – 411.357).

If these requirements are met, the waiver period commences on the start date of the ACO’s participation agreement under the MSSP, and ends on the earlier of the expiration of the participation agreement’s term (including renewals thereof) or the date on which the participation agreement is terminated. The Agencies are considering extending the time period for the waiver for another three to 12 months, and currently request comments on this approach.

Shared Savings Distributions Waiver

The shared savings distribution waiver¹⁰³ protects distributions of shared savings earned by the ACO through its MSSP participation to or among ACO participants or providers/suppliers, including compensation to outside parties for activities related to supporting the purposes of the MSSP. The waiver protects these distributions without risk of liability under the Stark Law, the Kickback Law and the Gainsharing CMP Law. No procedural requirements need to be met.

Waiver protection covers shared savings earned by the ACO while participating in the MSSP and distribution of those savings; duration of protection by this waiver is not based upon time/duration.

Patient Incentive Waiver

Finally, the patient incentive waiver¹⁰⁴ protects against liability under the Beneficiary Inducements CMP and the Kickback Law for free or below-market items or services provided by an ACO, the ACO participants, or the ACO providers/suppliers to

¹⁰¹ Interim final rule with comment period, 76 FR 67992, 68,001, Nov. 2, 2011.

¹⁰² To implicate the Stark Law, CMS appears to mean that the financial relationship must trigger the Stark Law’s referral and

billing prohibitions, and, therefore, must meet one of the Stark Law’s exceptions.

¹⁰³ Interim final rule with comment period, 76 FR 67992, 68,001, Nov. 2, 2011.

¹⁰⁴ *Id.*

Medicare beneficiaries that either (i) are preventive care items or services, or (ii) advance one or more of the following clinical goals: adherence to a treatment regime, adherence to a drug regime, adherence to a follow-up care plan, or management of a chronic disease or condition. Items and services must be provided by an ACO, its ACO participants, or its ACO providers/suppliers to Medicare beneficiaries whether assigned to the ACO or not.

Summary

The waivers under the Final ACO Waivers Rule are self-implementing; there are no filing or application procedures, and a *financial arrangement need only meet one of the waivers to be protected*. The Final ACO Waivers Rule will not be codified in the Code of Federal Regulations. Notably, the waivers only apply to ACOs with *bona fide* intent to, or actually participate in, the MSSP, including the Advance Payment Initiative of the Center for Medicare & Medicaid Innovation (the Innovation Center). Although the waivers do not apply to the Innovation Center's Pioneer ACOs, the Agencies have the authority to issue, and are expected to issue, similar and perhaps broader waivers for Pioneer ACOs as well as waivers for Innovation Center demonstrations.¹⁰⁵

¶25,530 Conclusion

Establishing an effective compliance program to oversee an accountable care organization's (ACO's) participation in the Medicare Shared Savings Program (MSSP) and reduce risks of program violations can be a daunting task. While an entity that is contemplating forming or joining an ACO may be able to rely on existing policies and standards that could apply to the ACO (*e.g.*, the compliance plan, certain quality reporting measures), there are other aspects of the MSSP that might be unfamiliar to the organization (*e.g.*, marketing requirements, beneficiary data sharing opt-out provisions). Each entity, alone and in conjunction with its proposed ACO partners, must evaluate where existing policies and procedures can sufficiently extend to participation in the MSSP and in what areas the entity must expand its oversight and operations. Given CMS' broad discretion to determine the eligibility of ACOs and terminate ACOs from the MSSP, potential ACO participants should thoughtfully consider how they plan to comply with the various MSSP requirements and how they will demonstrate such compliance to CMS.

[The next page is 30,001.]

¹⁰⁵ The Pioneer ACO Model is a program is designed for health care organizations and providers that are experienced in coordinating care for patients across care settings. It allows 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, MSSP. It 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. More information about Pioneer ACOs is available at <http://innovations.cms.gov/initiatives/aco/pioneer/>.