

The Controversial Draft Medicare ACO Regulations: Analysis, Comments and Recommended Action

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Section I. Background

Section 3022 of the Patient Protection and Affordable Care Act (ACA) requires the Secretary of Health and Human Services to establish the Medicare Shared Savings Program (MSSP) by January 1, 2012. The MSSP is based on the Physician Group Practice Demonstration and further incorporates the “shared savings” model of potential bonuses for eligible groups of providers that meet annual performance standards of quality health care services within per capita expenditures boundaries demarcated by the Centers for Medicare & Medicaid Services (CMS). Payment for covered services under MSSP would continue to be at Medicare fee-for-service (FFS) rates, with all of the fundamental elements of the Medicare FFS Program to be preserved.¹

On March 31, 2011, CMS issued Proposed Regulations under the ACA (the Proposed Regulations)^{2, 3} to implement the MSSP through the formation of Accountable Care Organizations (ACOs). This *White Paper* summarizes the major portions of the Proposed Regulations, and identifies issues for providers to consider in commenting and contemplating participation in a Medicare-sponsored ACO. CMS is expected to publish a final rule implementing Section 3022 later this year and in time for implementation on January 1, 2012.

ACOs create incentives for health care providers to work together to treat an individual patient across care settings. The MSSP will reward ACOs that lower growth in health care costs while meeting performance standards on quality of care. Patient and provider participation in an ACO is purely voluntary.⁴

Under the Proposed Regulations, an ACO that meets the MSSP’s quality performance standards would be eligible to receive a share of the savings it generates below a specific expenditure benchmark that would be set by CMS for each ACO. The Proposed Regulations would also hold certain ACOs accountable for downside risk by requiring ACOs to repay Medicare for a portion of losses (expenditures above its benchmark). To provide an entry point for organizations with varied levels of experience with risk sharing and desire to take on risk, the Proposed Regulations would allow an ACO to choose one of two program tracks. The first track would allow an ACO to operate on a “shared savings only” track for the first two years, but would then require the ACO to assume the risk for shared losses in the third year. The second track would require an ACO to share in both savings and risk liability for losses beginning in its first and subsequent performance years, in return for a higher share of any savings the ACO generates.

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- ☑ CMS’s analysis, set forth in the Regulatory Impact Analysis section of the Proposed Regulations (RIA), concludes that there will be quite significant costs borne to providers who form and participate in ACOs. CMS anticipates it will cost an ACO on average \$1.7 million to form and fund first-year operating expenditures needed to participate in the MSSP. CMS expects participation in the MSSP to require groups and providers to invest in or improve information technology systems, focus on evidence-based medicine, improve care coordination and quality, and generally refine all processes of caring for their patients. The estimates in CMS’s RIA are based heavily on the experience gained from an earlier CMS demonstration program, namely the Physician Group Practice (PGP) Demonstration, in which large, sophisticated physician groups with well-developed infrastructures and financial strength participated (it should be noted that a number of the PGP participants did not recover their investment in the PGP program, and also did not receive any shared savings payments from the PGP program). CMS is estimating that the return on infrastructure and start-up investment, in the form of shared savings bonus payments to ACO participants (estimated to number 75 to 150) will equal a median amount of \$800 million in the aggregate over the first three years of the MSSP.
- ☑ At least two groups have challenged CMS’s economic and financial estimates. An article in the *New England Journal of Medicine* concluded “that most organizations will lose money in the first 3 years under the ACO model” and noted that “. . . an ACO making the mean initial investment of \$1.7 million will require the unlikely margin of 20% for the 3-year period envisioned by CMS.”⁵ A second report, issued by the American Hospital Association (AHA), concluded that the start-up and ongoing operational costs for an ACO will be “between \$11.6 million [single hospital] and \$26.1 million [five hospital system],” noting that these amounts “should be viewed as a starting point for planning, not as a budget.” The AHA study was based on a series of case studies of organizations that have already taken steps to manage the care of a defined population in a manner similar to that of an ACO, and was completed prior to the release of the Proposed Regulations.⁶

Section II. Provisions of the Proposed Rule

A. Eligibility and Governance

1. ELIGIBLE ENTITIES

The Proposed Regulations provide that any of the following entities or groups may form an ACO: (a) ACO Professionals in group practice arrangements, (b) networks of individual practices of ACO Professionals, (c) partnerships or joint ventures between hospitals and ACO Professionals, (d) hospitals that employ ACO Professionals, and (e) critical access hospitals (CAHs) that bill under Method II (*i.e.*, CAHs that bill for *professional* medical services under a reassignment of benefits and are reimbursed at 115 percent of the Medicare Physician Fee Schedule amount, in addition to facility fees). CMS is proposing that Federally Qualified Health Centers (FQHCs) and Rural Health Centers (RHCs), as well as CAHs billing under Method I (which only bill for facility fees), cannot by themselves form ACOs because they do not report data for ACO Professionals upon which beneficiary attribution can be made.

CMS has solicited comments regarding (a) the kinds of providers and suppliers that should or should not be included as potential ACO participants, (b) the potential benefits or concerns with including or not including certain provider and supplier types, (c) the administrative measures that would be required to effectively implement and monitor certain partnerships, (d) other approaches to allowing independent providers and suppliers not mentioned in Section 3022 of the ACA to participate in ACOs (such as through an ACO formed by a group of FQHCs and RHCs), and (e) any operational issues associated with its proposal.

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- ☑ Other Medicare-enrolled providers and suppliers (including but not limited to FQHCs and RHCs) can participate in ACOs but cannot form them. In a sense, this is a distinction without a difference, because the ACO entity itself will submit an application to CMS to participate in the MSSP on behalf of its constituent ACO participants, including one or more of the five “permitted” types of participants and possibly many other types of ACO provider/suppliers. If so, each of these other ACO provider/suppliers may in reality have played an integral role in the formation of the ACO.
- ☑ In essence, CMS is requiring an ACO to be composed of primary care physicians practicing through an ACO entity to which beneficiary attribution can be made. Once that element is present, any other Medicare-enrolled providers and suppliers that have their own tax identification number (TIN), as well as non-providers such as health plans and management companies, may also participate in the ACO.

2. LEGAL STRUCTURE AND GOVERNANCE

a. *Legal Entity*

CMS has proposed that an ACO may be organized as any type of entity recognized under state law, including a corporation, partnership, limited liability company or foundation, that is capable of (a) receiving and distributing shared savings; (b) repaying shared losses; (c) establishing, reporting and ensuring ACO participant and ACO provider/supplier compliance with program requirements, including the quality performance standards; and (d) performing the other ACO functions identified in the ACA. The ACO must have its own TIN but need not be enrolled in Medicare. The ACO legal entity must be in good standing and duly qualified to transact business in each state in which it conducts operations.

Importantly, existing integrated entities that provide primary care services and meet the requirements for an ACO entity as described in the ACA and the regulations would not be required to form a separate legal entity to serve as the ACO. For example, under the Proposed Regulations, a hospital with employed physicians that is organized as a nonprofit corporation under applicable state law may contract directly with CMS to participate in the MSSP as an ACO, assuming that the hospital met the governance and other requirements discussed below. CMS acknowledges the relatively greater difficulty in auditing an entity that serves as more than just an ACO and solicits comments on whether or not such organizations should be required to form a separate legal entity to serve as the ACO. In any event, if the ACO will include ACO participants that are not

already part of its legal existing structure (e.g., independent physician practices) it must create a distinct legal entity to function as the statutorily required ACO entity.

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- ☑ It is not clear whether this means that the existing legal entity can be used only for those ACOs in which all constituent services are contained as divisions of a single corporate entity, or whether providers and suppliers that are under common control but organized as distinct legal entities could use their parent entity (e.g., a health system parent) or one of the existing constituent entities (e.g., the hospital or medical foundation) as the ACO contracting body, without the necessity of forming a new entity.

Each ACO would be required to certify to CMS that it is recognized as a legal entity under state law and authorized by applicable states to conduct business. The ACO would be required to furnish evidence in its application to support this certification. Presumably such proof would be in the form of a certificate of good standing issued by the entity's state of incorporation, as well as evidence of registration to transact business as a foreign entity in any other state in which the ACO conducts operations.

CMS is soliciting comments regarding other suitable legal structures that it should consider authorizing under the final rule or subsequent rulemaking. CMS has also requested input regarding whether the requirement to establish a separate legal entity for ACOs that include independent ACO participants is too burdensome, and what alternatives exist that will achieve the aim of shared governance and decision-making, and the ability to receive and distribute shared savings.

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- ☑ One concern presented by the requirement to establish a new legal entity is that such entities may be subject to certain state law requirements, such as having to obtain a third party administrator, insurance or HMO license, and/or otherwise be regulated as a risk-bearing organization. In states that impose such requirements (such as California, Colorado, Illinois, New Jersey, New York, Ohio and Pennsylvania), it may be beneficial for an ACO that includes an appropriately state-licensed entity to use that licensed entity as the ACO contracting entity, since that entity would already meet these requirements.
- ☑ Recognition of an ACO as exempt under Section 501(c)(3) of the Internal Revenue Code (the Code) would greatly facilitate the ability of a charitable hospital to provide infrastructure funding for an ACO. Unfortunately, IRS Notice 2011-20 provides very little insight on this question. The Internal Revenue Service (IRS) has generally taken the position that physician-hospital organizations (PHOs) were not eligible for exemption because negotiating managed care contracts for the member-physicians furthers their private interests more than incidentally. Notice 2011-20 reiterates this, noting that "negotiating with private health insurers on behalf of unrelated parties generally is not a charitable activity, regardless of whether the agreement negotiated involves a program aimed at achieving cost savings in health care delivery." On the other hand, if the IRS does not equate ACOs to PHOs, exemption for ACOs under the community benefit standard under Section 501(c)(3) of the Code may be possible. In a variety of rulings (both precedential and non-precedential) involving various other types of health care entities, the IRS has provided a list of favorable factors relevant to the community benefit analysis, which should be applicable to seeking tax-exempt status. The fact that an ACO contracting entity would not provide health care services does not preclude it from qualifying as a Section 501(c)(3) organization under the community benefit standard. In other words, the direct provision of medical, hospital or nursing care to individuals is *not* the exclusive means by which an organization can establish that it promotes health for the benefit of the community within the meaning of Section 501(c)(3). In addition, ACO entities organized as nonprofit corporations may conceivably be able to qualify for tax exemption under a "lessening the burdens of government" rationale. IRS Notice 2011-20 is helpful in this regard, as it does explicitly acknowledge that the MSSP is intended to lessen the burdens of government.

- ☑ The choice of corporate form will be affected by a number of factors. For example, if any ACO were to develop valuable intellectual property (e.g., care models, pricing models, software), the ACO owners could incur considerable tax liability upon the dissolution of an ACO that is organized as a subchapter C corporation if there is significant gain in the value of that intellectual property. This would not be the case if the ACO were organized as a partnership or limited liability company that elects pass-through tax treatment. Generally, a pass-through entity that offers liability protection, such as a limited liability company, would be a preferred vehicle for an ACO. However, use of a pass-through entity can complicate retention of earnings, since the owners require distributions of cash to meet their tax obligations. The companion guidance issued by the Internal Revenue Service, Notice 2011-20, does state that an exempt organization's participation in an ACO that contracts with CMS under the MSSP generally should not result in inurement or excessive private benefit or the recognition of unrelated business income. This removes the concern that structuring an ACO as a pass-through entity could jeopardize a tax-exempt participant's basis for its own exemption under a "primary purposes" test, as a result of the pass-through ACO entity's activities being attributed to the exempt ACO participant. It is an open question whether an ACO organized as a nonprofit corporation could be recognized as exempt for federal and state income tax purposes.

b. Governance

The Proposed Regulations contain a series of explicit governance requirements that would be applicable to an ACO. ACO governance-related requirements are based upon the theme of shared governance (with proportionate control) among ACO participants. The governance body may be styled as a board of directors, a board of managers, or any other governing body that provides a means for shared governance and decision-making for all ACO participants, and that has the authority to execute the statutory functions of the ACO. Specifically, the ACO governance body must have and maintain authority sufficient to carry out the key functions of an ACO as identified by the Proposed Regulations. These include the definition of processes to (a) promote evidence-based medicine and patient engagement, (b) report on quality and cost measures, and (c) coordinate care.

The Proposed Regulations also address two provisions related to corporate governance: the establishment of (a) a physician-directed quality assurance and process improvement committee responsible for oversight of a quality assurance and improvement program, and (b) a compliance plan. The compliance plan must include the following key elements: (a) a chief compliance officer (not the ACO's legal counsel) who has the authority to report directly to the ACO Board; (b) mechanisms for identifying and directing ACO operational and performance-related compliance programs; (c) a "whistleblower"-type reporting mechanism; (d) compliance training for the ACO, its participants and its suppliers/providers; and (e) a particularly controversial requirement to report suspected legal violations to an appropriate law enforcement agency.

The Proposed Regulations acknowledge that the specific design and structure of an ACO's compliance plan will depend upon the size and business structure of the ACO. Furthermore, an ACO's compliance efforts may use or build upon an existing compliance program. For example, the ACO may want to coordinate its compliance efforts with those of its ACO providers/suppliers; the ACO need not engage in duplicative compliance efforts.

3. LEADERSHIP AND MANAGEMENT

The ACO's leadership and management structure must be managed by an executive, officer, manager or general partner whose appointment and removal are subject to the authority of the ACO board, and whose leadership team has experience in influencing or directing ("has demonstrated the ability to influence or direct") clinical practice to improve efficiency processes and outcomes. Clinical management is to be the responsibility of a full-time senior-level medical director who must be physically present in an established ACO location and who is a board-certified physician licensed in the ACO's state of operation.

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- ☑ *Board Composition.* The ACO board must be composed of the following constituents: (a) the ACO participants or their designated representatives, and (b) one or more disinterested representatives of the Medicare beneficiary community served by the ACO.
- ☑ *Board Authority.* The board must possess "broad responsibility" for the administrative, fiduciary and clinical operations of the ACO.

- ☑ *Board Control.* ACO participants must be assigned no less than 75 percent of board control. Each ACO participant is to appoint an “appropriate” organizational representative to represent it on the ACO board. Control over ACO decision-making should be allocated among the ACO participants on a proportionate basis.
- ☑ *Special Board Structure Issues.* ACO board members are not precluded from serving in a similar or complementary manner with an existing ACO participant. In those situations where the ACO comprises multiple distinct entities (e.g., several separate “independent practice associations”), the governing board of the ACO must remain separate and distinct from the boards of those other entities. A separate governing body must be established for the ACO (except in certain limited circumstances). The ACO application to CMS must include evidence that the ACO board is a “separate legal entity.”
- ☑ *Single Entity Exception.* In situations where the ACO is owned by a discrete legal entity that is clinically and financially integrated and has a governing board that itself satisfies the 75 percent representation requirement of the Proposed Regulations, then the ACO governing board may be the same as that entity’s board (provided that the entity’s board satisfies the other ACO governance requirements of the Proposed Regulations).
- ☑ *Conflicts of Interest Policy.* The ACO board must adopt a conflicts of interest policy designed to make sure that its board members act in the best interests of the ACO and its Medicare beneficiaries. This policy will require disclosure of the relevant financial interests of board members, and must also include provisions for (a) determining whether a conflict of interest exists, (b) a process to address any conflict that may arise and (c) remedial actions for board members who fail to comply with the conflict policy.
- ☑ The Proposed Regulations seek comments on a number of governance-related provisions, including those relating to (a) patient involvement in ACO governance, (b) the requirement that at least 75 percent control of the ACO board must be vested in ACO participants, (c) whether the appropriate representatives should be held by persons employed by and representing Medicare-enrolled TINs, (d) the scope and content of the ACO board’s conflict of interest policy, and (e) whether the proposed governance requirements might actually serve as a disincentive for ACO formation.

4. ACCOUNTABILITY FOR BENEFICIARIES

Section 3022(b)(2)(A) of the ACA requires participating ACOs to be “willing to become accountable for the quality, cost and overall care of the Medicare fee-for-service beneficiaries assigned to it.” For ACOs to meet this requirement, CMS has proposed that an executive from each participating ACO with the authority to bind the ACO (the ACO Executive) be required to certify, to the best of his or her knowledge, information and belief, that the ACO participants are willing to be accountable for, and report to CMS on, the quality, cost and overall care of the beneficiaries assigned to the ACO. Such certification would be included in the ACO application and the ACO’s participation agreement.⁷ Each ACO would also be required to make information publicly available, in a standard format as determined by CMS,⁸ relating to its accountability for quality, cost and overall care of its assigned beneficiaries.

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- ☑ This provision could be viewed as relatively benign; presumably it can be assumed that the ACO participants are willing to agree to these requirements or they would not be voluntarily participating in the ACO in the first instance. However, it is of concern that CMS does not indicate whether the ACO Executive can rely on such affirmative conduct in making the certification or to what degree CMS expects an ACO Executive to obtain some unspecified form of written confirmation from the ACO’s participants prior to making the certification. At a minimum, the ACO’s contracts with participants should include a provision to that effect.
- ☑ As a practical matter, any such required “certifications,” and the potential personal liability they entail, may have a “chilling effect” on the willingness of otherwise qualified individuals to serve in that capacity, or may have the effect of requiring ACOs to pay more for their services than would otherwise be required, in order to attract qualified executives.

5. AGREEMENT REQUIREMENT

While Section 3022(b)(2)(B) of the ACA requires participating ACOs to “enter into an agreement with the Secretary to participate in the program for not less than a 3-year period . . .,” CMS is proposing a three-year term for all ACO agreements, and is seeking commentary on whether longer agreements should be considered.⁹ Once the ACO is approved for participation and ready to submit an agreement, the ACO Executive would be required to certify, to the best of the ACO Executive’s knowledge, that the ACO participants agree to the requirements in the agreement.¹⁰ The ACO Executive is required to sign the agreement and submit it to CMS, along with an acknowledgment that the ACO agrees to comply, and that all of its arrangements relating to the ACO (including with ACO suppliers, providers, service agreements, etc.) will comply, with all requirements for participation in the MSSP.¹¹ The ACO is responsible for providing a copy of the agreement to its ACO participants and ACO providers/suppliers.¹²

As described further in the discussion below regarding Monitoring and Termination of ACOs, if an ACO decides it cannot participate for the entire term of the agreement, the ACO is required to provide at least 60 days’ advance written notice of its intention to terminate its agreement early and the effective date of such early termination.¹³ Since all ACOs are now required to participate in the two-sided risk model, at least by the third year of their contract, CMS is proposing to withhold 25 percent of shared savings to protect Medicare against any future losses. CMS is proposing that, if an ACO completes its three-year agreement “successfully,” CMS will refund any such shared savings withheld to the extent not needed to offset the ACO’s losses. If, however, the ACO terminates its agreement early, the ACO would forfeit all withheld amounts in order to offset any future losses.¹⁴

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- ☑ Providers and suppliers gearing up for the arrival of ACOs generally are investing in accountable care for the long term. It is unclear whether anything significant can be read into CMS’s proposed three-year flat term for ACOs at this time, but certainly ACO participants should press for more long-term commitments, given the substantial efforts being undertaken to form ACOs.
- ☑ Much like the concept of “Business Associates” under HIPAA, CMS is proposing to require that ACOs require compliance with the MSSP requirements not only by ACO participants but also by downstream contractors.

6. DISTRIBUTION OF SAVINGS

CMS is proposing to make any shared savings payments directly to the ACO, as identified by its TIN. At this time, CMS is not requiring that the TIN associated with the ACO’s legal entity be enrolled in the Medicare program, although the ACO’s participants would be required to be Medicare-enrolled. While this creates a potential obstacle for recoupment of overpayments, CMS is seeking to mitigate such risk through the payment withhold discussed below.

CMS proposes to require ACOs to provide a description in their application of the criteria they plan to employ for distributing shared savings among ACO participants and ACO providers/suppliers, and how any shared savings will be used in a manner consistent with the principal aims of the ACO program: better care for individuals, better health for populations and lower growth in expenditures.¹⁵ ACOs are to include this description in the application, so that CMS can ensure that there are no improper financial incentives, and that appropriate beneficiary protections are present.

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- ☑ At the outset, it may be difficult to determine how shared savings should be distributed in a manner that ensures both the financial viability of the ACO and the active participation of its participants. Will the ACO be bound by its submitted plan during the initial contract year (or the entire three-year term), or will there be flexibility to adapt and change as the ACO’s experience with the MSSP and among its own participants evolves?
- ☑ Where an ACO itself is not enrolled in Medicare, to the extent there is liability or monies owed back to Medicare based on downside risk, the government is likely to try to “pierce” the ACO and look to its Medicare-enrolled participants to pay the financial obligations of the ACO. This may well have a “chilling effect” on the willingness of providers to participate in the ACO, particularly in the full two-sided risk model.

7. SUFFICIENT NUMBER OF PRIMARY CARE PROVIDERS AND BENEFICIARIES

Section 3022(b)(2)(D) of the ACA requires participating ACOs to “include primary care ACO professionals that are sufficient for the number of Medicare fee-for-service beneficiaries assigned to the ACO . . .” and that at a minimum, “the ACO shall have at least 5,000 such beneficiaries assigned to it . . .” CMS is proposing to assign beneficiaries to an ACO on the basis of primary care services rendered by physicians with primary care specializations in general practice, internal medicine, family practice and geriatrics. CMS is proposing that an algorithm also be used to assign beneficiaries during the baseline years in order to establish a historical per capita cost benchmark against which the ACO would be evaluated during each year of the agreement. CMS believes that if the ACO demonstrates a sufficient number of beneficiaries to fulfill this eligibility requirement for purposes of establishing a benchmark, then the ACO would automatically have a sufficient number of primary care professionals to provide care to these beneficiaries. CMS also believes it is reasonable to assume that the ACO would continue to approximate this number of beneficiaries in each year of the agreement period. Thus, an ACO would be determined to have a sufficient number of primary care ACO professionals to serve the number of Medicare beneficiaries assigned to it if the number of beneficiaries historically assigned to primary care providers within the ACO over the three-year benchmarking period, using the ACO participant TINs, exceeds the 5,000 threshold for each year.

The 5,000 minimum beneficiary threshold is deemed by the ACA and CMS to be the “critical mass” from both the perspective of the capacity of the ACO to provide primary care services to its assigned beneficiary population and the ability of the ACO to realize shared savings by exceeding the Minimum Savings Rate (MSR). However, CMS acknowledges that the number of beneficiaries assigned to an ACO will vary over time, and is seeking to balance the statutory minimum requirement while not unduly punishing or discouraging ACO participation, particularly among smaller ACOs. To balance these concerns, CMS is proposing that, if an ACO’s assigned population falls below 5,000 during the course of its agreement, CMS would issue a warning and place the ACO on a corrective action plan, which may include, for example, a plan to attract additional primary care physicians. The ACO would remain eligible to receive shared savings for the performance year for which the warning was issued. However, if the ACO fails to have more than 5,000 beneficiaries by the completion of the next performance year, the ACO’s agreement will be terminated, and the ACO will not be eligible to share in savings that year. CMS also proposes to reserve the right to review the status of the ACO while it is subject to the corrective action plan and to terminate the agreement on the basis that the ACO no longer meets eligibility requirements.

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- ☑ The issue of beneficiary assignment and the lack of ability of an ACO to “lock in” or even financially incentivize beneficiaries to stay within the ACO provider network for their care, and thus exercise effective control over the beneficiaries for whom the ACO will be held accountable, represents a fundamental concern and challenge for ACOs. “Snowbirds” will create particular problems in this regard.
- ☑ For ACOs that are not as large or that do not have significant physician practices committed to the ACO (or its other participants) for the long term, the ability to maintain the required minimum beneficiary threshold and minimum number of primary care providers needed to serve those beneficiaries represents a significant challenge.
- ☑ Primary care physicians are critical to the viability, let alone the success, of the ACO. However, primary care physicians are already in short supply in many areas, with the shortage predicted to increase significantly over the coming years. Moreover, primary care physicians are disadvantaged financially compared to specialists. They are commonly excluded from or otherwise unable to participate in many physician-hospital ventures, and typically are paid much less than most specialists. The ACO model re-emphasizes the importance of primary care physicians as a group and gives them new leverage, as they are the focal point of this industry-wide initiative.

8. PROCESSES TO PROMOTE EVIDENCE-BASED MEDICINE, PATIENT ENGAGEMENT, REPORTING AND COORDINATION OF CARE

Section 3022(b)(2)(G) of the ACA requires an ACO to “define processes to promote evidence-based medicine and patient engagement, report on quality and cost measures, and coordinate care, such as through the use of telehealth, remote patient monitoring, and other such enabling technologies.” CMS is proposing that, in order to be eligible to participate in the MSSP, the ACO provide documentation in its application describing its plans to (a) promote evidence-based medicine, (b) promote beneficiary engagement, (c) report internally on quality and cost metrics, and (d) coordinate care.¹⁶ CMS believes this approach will allow an ACO the flexibility to meet these requirements in a manner that is most appropriate for its particular practitioners and patient populations. At the same time, CMS reserves the right to revise these requirements as essential elements

for ACO success come to light with ACO experience. CMS is seeking comment on whether more defined criteria are appropriate.

a. Processes to Promote Evidence-Based Medicine

Evidence-based medicine can be generally defined as the application of the best available evidence gained from the scientific method to clinical decision-making. In practice, CMS believes that such an approach should involve the establishment and implementation, at the organizational or institutional level, of evidence-based guidelines, based on the best available evidence concerning the effectiveness of medical treatments (including the lack of treatment). CMS's proposed evidence-based approach would also involve regularly assessing and updating such guidelines to promote continuous improvement in the quality of care in light of new evidence concerning the effectiveness of medical treatments.

ACTION ITEM

- CMS proposes that, as part of the ACO's application, the ACO describe the evidence-based guidelines it intends to establish, implement and periodically update.

b. Processes to Promote Patient Engagement

Section 3022 (b)(2)(G) of the ACA also requires an ACO to define processes to achieve "patient engagement." According to CMS, the term "patient engagement" means the active participation of patients and their families in the process of making medical decisions. Patient engagement in decision-making requires not only consideration of the best scientific evidence concerning medical treatment but also the opportunity for patients and families to assess prospective treatment approaches in light of their own values and convictions. Measures for promoting patient engagement may include the use of decision support tools and shared decision-making methods with which the patient can assess the merits of various treatment options in the context of his or her needs, preferences and values. Patient engagement also includes methods for fostering "health literacy" or basic knowledge about maintaining good health, avoiding preventable medical conditions, managing existing conditions and understanding how the care system works.

ACTION ITEM

- CMS proposes that, as part of the ACO's application, the ACO describe the patient engagement processes it intends to establish, implement and periodically update.

c. Processes to Report on Quality and Cost Measures

Section 3022 (b)(2)(G) of the ACA requires an ACO to "define processes to . . . report on quality and cost measures." According to CMS, processes that may be used for reporting on quality and cost measures may include, but are not limited to, developing a population health data management capability or implementing practice and physician level data capabilities with point-of-service (POS) reminder systems, to drive improvement in quality and cost outcomes.

ACTION ITEM

- CMS proposes that, as part of its MSSP application, the ACO describe its process to report internally on quality and cost measures, and how it intends to use that process to respond to the needs of its Medicare population and to make modifications in its care delivery.

d. Processes to Promote Coordination of Care

Section 3022(b)(2)(G) of the ACA requires an ACO to "define processes to . . . coordinate care, such as through the use of telehealth, remote patient monitoring, and other such enabling technologies." Coordination of care involves strategies to promote, improve and assess integration and consistency of care among primary care physicians, specialists, and acute and post-acute providers and suppliers, including methods to manage care throughout an episode of care and during its

transitions, such as discharge from a hospital or transfer of care from a primary care physician to a specialist. CMS provides a laundry list of proposed strategies that may be used to comply with this standard. These include predictive modeling, utilization of case managers in primary care offices, transition of care programs, remote monitoring, telehealth and focused health information technology allowing for the seamless transition of a beneficiary's records within and outside of the ACO.

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- ☑ The provision of any free services (e.g., case managers onsite at a primary care office) could trigger fraud and abuse laws.

CMS warns that the strategies employed by an ACO to optimize care coordination should not impede the ability of a beneficiary to seek care from providers that are not participating in the ACO, nor otherwise place restrictions that are not legally required on the exchange of medical records with providers who are not part of the ACO. CMS proposes to prohibit the ACO from developing any policies that would restrict a beneficiary's freedom to seek care from providers and suppliers outside of the ACO.

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- ☑ CMS's proposals regarding "Processes to Promote Evidence-Based Medicine, Patient Engagement, Reporting, and Coordination of Care" make clear that this aspect of ACOs and the related goals are still a work in progress. At this time, CMS is not requiring specific parameters or providing significant guidance with respect to how ACOs propose to implement these aspects and goals of the MSSP. While the lack of guidance gives ACOs flexibility in how they approach these items in their applications, it also leaves ACOs without any assurance that their proposals will meet CMS's standards.
- ☑ In whatever manner an ACO plans to address these aspects of ACO compliance, it will be important for the ACO to coordinate with its participants and other stakeholders, and especially with beneficiaries, in this process. The physicians and health system or hospital participants will be in the best position to monitor advances in evidence-based medicine and incorporate them into the standard ACO protocols. The beneficiaries, physicians, support personnel and others will be essential to ensure beneficiary (and family/caregiver) engagement in the process as well as coordination of care.
- ☑ With respect to coordination of care, CMS's proposals again underscore a disconnect: on the one hand, more resources will be needed; on the other, providing those resources can leave participants exposed to fraud and abuse allegations and related issues. As the ACO concept evolves, it is hoped that more clarity and a more unified government front to address these competing interests in a more global and predictable manner will also develop. In the meantime, ACOs and their participants must realize that participation in the MSSP is not a shield from other federal and state health care laws, and each step taken must be carefully and critically analyzed under current guidance from all perspectives.

9. PATIENT-CENTEREDNESS CRITERIA

Section 3022(b)(2)(H) of the ACA requires an ACO to demonstrate that it meets "patient-centeredness criteria specified by the Secretary, such as the use of patient and caregiver assessments or the use of individualized care plans." CMS proposes a list of patient-centeredness principles to guide the care provided by a participating ACO, including (a) care being individualized for each patient, (b) beneficiaries having access to their medical records and sufficient clinical knowledge (or evidenced-based medicine) to make informed choices about their care, (c) beneficiaries being encouraged to be partners in care and make choices regarding the care they receive, (d) assessing beneficiary (and caregiver) experience and identifying opportunities for improvement, (e) integrating care with the community resources required to maintain beneficiary well-being, and (f) coordinating transition in care among providers both inside and outside of the ACO.

In the Proposed Regulations, CMS sets an aspirational requirement that the ACO "should" adopt a focus on patient-centeredness that is promoted by the governing body and integrated into practice by leadership and management working with the organization's health care teams.¹⁷ CMS then proposes the following nine specific criteria that each ACO must have to meet the "patient-centered" requirement:

- A beneficiary experience survey in place and a description of how the ACO will use the survey results to improve quality over time. CMS is currently proposing to require that every ACO use the Clinician and Group CAHPS survey, including an appropriate functional status module.

- Beneficiary involvement in its governance (as detailed below, this could be met by having the requisite beneficiary member(s) of the ACO's governing board).
 - A process for evaluating the health needs of its assigned population, including consideration of diversity, and a plan to address the needs of its population.
 - Systems to identify and update high-risk individuals, and processes to develop individualized plans for targeted patient populations, including integration of community resources to address individual needs. Such plans must promote improved outcomes for high-risk, multiple-chronic-condition patients and other patient populations, as appropriate. The plans also must be tailored to the beneficiary's needs, preferences and values, and include community resources to support the beneficiary's success with the plan.
 - A mechanism in place for the coordination of care. The ACO must describe this mechanism and should have a process in place (or a clear path to develop such a process) to exchange summary of care information when beneficiaries transfer to other providers (whether within or outside of the ACO). For providers enrolled in the electronic exchange of information, the process must be consistent with meaningful use requirements.
 - A process for communicating clinical knowledge in a way that is understandable to beneficiaries.
 - A process for beneficiary engagement in the decision-making process that is tailored to the needs and preferences of the beneficiary.
 - Written standards for beneficiary access and communication, and a process for beneficiaries to access their medical record.
 - Internal processes for measuring clinical or service performance by physicians across the practices, and for using these results to improve care and service over time.
- a. *Beneficiary Experience of Care Survey*

CMS proposes that ACOs have a beneficiary experience of care survey and that an ACO's application should describe how the ACO would use the survey results to improve patient care over time. As noted above, CMS proposes that ACOs be required to use the Clinician and Group CAHPS survey, with an appropriate functional survey module, to assess beneficiary experience of care and functional status. Scoring on the patient experience of care survey would become part of the assessment of ACOs' quality performance. CMS proposes to require ACOs to collect and report on measures of beneficiaries' experience of care, and ACOs will be expected to submit to CMS their plan on how they will promote, assess and continually improve in weak areas identified by the survey.

b. *Patient Involvement in Governance*

Another of the proposed patient-centered criteria is the requirement that ACOs provide for patient involvement in their governing processes. To satisfy this criterion, ACOs will be required to have a Medicare beneficiary serviced by the ACO participate in the ACO governing body (CMS specifically discounted—subject to commentary being sought—the idea of an advisory committee, determining that approach to be inadequate to ensure beneficiary participation.) No beneficiary included in an ACO's governing body, or an immediate family member, may have any conflict of interest (other than, presumably, the conflict that inherently arises from their being a patient or potential patient of the ACO), and they may not be an ACO provider/supplier within the ACO's network.

CMS is soliciting comment on whether there should be a minimum standard for such beneficiary participation on ACO governing bodies (e.g., a minimum proportion of control over an ACO's governing body), and whether (a) a Medicare beneficiary advisory panel or committee would be sufficient for appropriate patient participation in ACO governance, and (b) Medicare beneficiary advisory panels or committees also should be required.

c. *Evaluation of Population Health Needs and Consideration of Diversity*

ACOs must have a process for evaluating the health needs of the population, including consideration of diversity in their patient populations, and a plan to address the needs of their populations. CMS proposes that, in order to satisfy this patient-centered criterion, an ACO be required to describe in the application its process for evaluating the health needs of its Medicare population, including consideration of diversity, and a plan to address the needs of its Medicare population.

d. *Implementation of Individualized Care Plans and Integration of Community Resources*

CMS is proposing that ACOs must have systems in place to identify high-risk individuals and processes in order to develop individualized care plans for targeted patient populations. The plan must (a) be tailored to the beneficiary's health and psycho-social needs; (b) account for beneficiary needs, preferences and values; and (c) identify community and other resources to support the beneficiary in following the plan. This plan would be used solely by the patient and ACO providers/suppliers for care coordination. If applicable, and if the beneficiary consents, the care plan should be shared with the caregiver(s), family and others involved in the beneficiary's care. An ACO would be required to have a process in place for developing, updating and, as appropriate, sharing the beneficiary care plan with others involved in the beneficiary's care, and providing it in a format that is usable by the beneficiary. In order to satisfy this requirement fully, individualized care plans should be a result of shared decision-making that fully engages beneficiaries and their families, taking into account their values and preferences in developing a unique plan of care for each individual. The individualized care plans should include identification of community and other resources to support the beneficiary in following the plan. An ACO would be required to submit a description of its individualized care program, along with a sample care plan, and to explain how this program is to be used to promote improved outcomes for, at a minimum, its high-risk and multiple chronic condition patients. In addition, the ACO should describe additional target populations that would benefit from individualized care plans. Under the Proposed Regulations, the ACO would also be required to describe how it would partner with community stakeholders as part of its application. ACOs that have a stakeholder organization serving on their governing body would be deemed to have satisfied this requirement.

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- ☑ The proposal to utilize the CAHPS survey as the exclusive option for a survey tool to assess beneficiary experience is a nod to uniformity and simplicity, but would exclude other good tools. Additionally, providers that currently utilize other tools may feel that their historic data collection may not match up well with the information obtained through CAHPS, thus costing them part of the benefit of their past efforts.
- ☑ Additionally, while the "patient centeredness" requirements are set forth in the Proposed Regulations, there is not a lot of meat on the bones for each requirement. While there is a clear path to complying with some (e.g., having a beneficiary on the governing board of the ACO), others offer little guidance regarding what is required for the ACO to comply. CMS will likely continue to develop these requirements over time. In the meantime, it is clear that CMS wants to ensure that ACOs are focused on their beneficiaries' needs, including planning for high-risk patients and the diversity of patient populations, as well as making beneficiaries active and knowledgeable participants in their care. Successful ACOs will do well to go beyond the minimum requirements of beneficiary participation and coordination of care, and make it a core principle to ensure the accountable care being provided is the result of the collective efforts of the ACO participants, beneficiaries, their families and other stakeholders.

10. ACO MARKETING GUIDELINES

Consistent with its patient-centered focus, CMS highlights its concern that beneficiaries may be misled about the benefits of and services available from an ACO. To protect against these concerns, CMS proposes to require that all ACO marketing materials, communications and activities related to the ACO and its participation in the MSSP (and any changes to these materials) be subject to CMS approval, similar to those requirements that govern marketing materials under Medicare Advantage and Medicare Part D. For purposes of this section, CMS defines "marketing materials" to include general audience materials such as brochures, advertisements, outreach events, letters to beneficiaries, web pages, mailings or other activities. CMS includes any such materials or marketing activities used by ACO participants or ACO providers/suppliers on behalf of the ACO. Informational materials, non-ACO related pieces, referrals, billing/claims communications and medical-condition-related mailings (e.g., regarding flu shots) are not marketing materials subject to approval by CMS. ACOs that fail to adhere to CMS's marketing guidelines may be placed under a corrective action plan, or may be subject to termination from the MSSP, at CMS's discretion.

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- ☑ Organizations that have not been previously required to submit marketing materials to CMS for approval will face a significant learning curve in order to comply with these ACO marketing guidelines. 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 the precise permissible font sizes, footnote placement and required disclosures. ACOs will need to build in lead time for the development of these materials to allow for CMS's approval, and also be prepared to make revisions if necessary.

11. PROGRAM INTEGRITY REQUIREMENTS

Some of the more glossed-over provisions set forth in the Proposed Regulations are the provisions designed to protect the MSSP from fraud and abuse. However, organizations contemplating establishing an ACO should be mindful of these requirements, given CMS's increased enforcement in this area. First, CMS proposes to require that ACOs adopt a compliance plan that includes at least the following five elements:

- 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
- A requirement to report suspected violations of law to an appropriate law enforcement agency

There is no need to duplicate efforts to the extent the applicant organization already has a compliance program in place that satisfies these requirements (*e.g.*, a hospital-owned ACO applicant's compliance officer and program should suffice), so long as the ACO can demonstrate that its compliance mechanisms are "effective."

Second, CMS emphasizes that ACOs maintain ultimate responsibility for compliance with all terms and conditions of their agreement. To ensure that all entities that participate in an ACO remain committed to complying with the MSSP requirements, CMS proposes to require that all contracts between an ACO, its ACO participants, and ACO providers and suppliers, or other entities furnishing services related to ACO activities, mandate that the contracting entities comply with the ACO program requirements. Further, CMS will require an authorized representative of the ACO, with authority to legally bind the ACO, to certify the accuracy, completeness and truthfulness of the information contained in the (a) MSSP application, (b) agreement with CMS, and (c) quality and other data submitted 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.

Third, CMS proposes to require that ACOs have a conflicts of interest policy in place that applies to members of the ACO's governing body and that requires members to disclose relevant financial interests, so that the ACO may determine whether a conflict exists. The policy must also include remedial actions for members of the governing body who fail to comply with this requirement. However, CMS 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.

Fourth, because ACOs will not be subject to CMS existing provider enrollment screening, CMS is considering conducting individual screens on the ACO application process with regard to the program integrity history of participants, including the history of any program exclusions or other sanctions, as well as any affiliations with individuals or entities that have a history of program integrity issues.

Finally, CMS proposes to prohibit ACOs from conditioning participation in the ACO on referrals of federal health care program business that the ACO or ACO participants know or should know is being provided to beneficiaries who are not assigned to the ACO. CMS is particularly concerned about the risks of abuse if it ends up assigning beneficiaries to an ACO on a prospective basis at the beginning of a performance period.

B. The Start Date for the ACO Agreement

Section 3022 of the ACA provides that an ACO is to enter into an agreement to participate in the MSSP for no fewer than three years. To implement this provision, the Proposed Regulations address the start date for the three-year agreements and the associated application evaluation period.

In considering various start date options (annual, semi-annual, rolling and delayed), CMS focused on striking an appropriate balance between affording flexibility to program applicants and achieving streamlined administration of the application process. The Proposed Regulations adopt an annual, calendar-year approach to both the start date and the application evaluation period, under which (a) CMS would establish a deadline for submission of ACO applications, (b) CMS would review applications prior to the end of the calendar year in which they were received, (c) the three-year period under each agreement would begin on the January 1 following approval of the application, and (d) each performance period would begin on January 1 of each year under the three-year agreement.

CMS chose this approach in large part because of the January 1, 2012, deadline for establishment of the MSSP and the difficulties other approaches presented for the assignment of beneficiaries to an ACO. However, CMS also invites comment on other approaches to the January 1 start date that would allow the greatest number of participants to apply for participation in the first year (2012) of the MSSP.¹⁸

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- The Proposed Regulations are silent with regard to whether CMS will develop a standard MSSP application.
- It now appears unlikely that CMS will hold hard and fast to the January 1, 2012, start date for the initial MSSP agreement, particularly in light of the recent reports that the nature and extent of the comments and criticism CMS has received to date will likely delay publication of the final MSSP regulations.

1. EFFECT OF CHANGES THAT OCCUR DURING AN ACO AGREEMENT'S THREE-YEAR PERIOD

The Proposed Regulations address the potential effect of two types of changes that could occur during the current three-year term of an ACO agreement: (a) program changes made by CMS, and (b) other changes that can cause the ACO to deviate from the basis for eligibility presented in its application.

a. *Program Changes by CMS*

In attempting to balance the risk that CMS-initiated changes will affect an ACO's continued eligibility with the benefits of achieving consistency and ease of administration of eligibility requirements, CMS proposes that ACOs be subject to all future program changes by CMS except those affecting (a) eligibility requirements concerning an ACO's structure and governance, (b) calculation of the shared savings rate, and (c) assignment of beneficiaries. Therefore, during the term of its agreement with CMS, an ACO would need to be prepared to accept and adapt to regulatory changes in areas such as quality measures and quality management, program integrity requirements, patient engagement processes and patient-centeredness criteria that may necessitate changes in how the ACO designs and delivers care. In the event that such changes are implemented by CMS, an ACO would be required to provide CMS with a supplement to the ACO's original application explaining how the ACO will address such changes; failure to do so could trigger the need to file a corrective action plan or could lead to termination of the agreement, or eventually both.

b. *Other Changes*

CMS describes several types of changes other than those made by CMS that could affect an ACO's current MSSP agreement, including changes in governance structure or leadership; provider composition; beneficiary population; key processes pertaining to the design, delivery and quality of care (*e.g.*, processes for quality management and patient engagement and patient-centeredness criteria); and planned distribution of savings. CMS expresses particular concern over changes in provider composition that could require additional antitrust review or re-review. Specifically, the Proposed Regulations prohibit an ACO from adding participants during the three-year period covered by its agreement, but permit the ACO to remove participants or to add or remove non-participant provider/suppliers. The ACO must notify CMS of any significant changes within 30 days, and CMS will then conduct a review. The possible outcomes of CMS's review include the termination of the agreement and forfeiture of savings earned, the ACO being subjected to a new antitrust review, the application of a new three-year agreement, and the recalculation of the ACO's savings based on the updated list of participants and providers/suppliers. CMS and the ACO may also mutually agree to terminate the ACO agreement.

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- ☑ What if there are compelling and appropriate reasons for an ACO to add a participant, such as the loss of key primary care physicians? It is difficult to understand why CMS did not allow the addition of a participant with prior CMS approval, but perhaps in practice this could be accomplished through a waiver.

CMS proposes that ACOs that experience a loss in their first three-year agreement and ACOs that were terminated for program integrity failures (*e.g.*, avoidance of at-risk beneficiaries) be barred from future participation in the MSSP. Voluntary or forced termination of an agreement for other reasons would not necessarily bar future participation. However, all applications for three-year agreements must disclose information to enable CMS to determine whether the applicant previously participated in the ACO program, the basis for termination of a prior agreement, and the safeguards the ACO has established to enable participation for the full three-year period under the new agreement. Further, a new three-year agreement may not begin until the three-year period under the prior agreement has lapsed.

2. TIMING AND PROCESS FOR EVALUATING SHARED SAVINGS PERFORMANCE

Section 3022 of the ACA also provides that an ACO shall be eligible to receive shared savings payments for each year of the agreement's three-year period if it meets the quality performance standards established under the ACA and achieves the required percentage of savings benchmark. In considering the timing for evaluating shared savings eligibility, CMS focused on striking the appropriate balance between providing timely performance feedback and achieving accuracy in the claims data used to calculate the per capita shared savings achieved. It proposed the use of a six-month "claims-run-out period"¹⁹ to calculate the performance benchmark and per capita expenditures for the performance year, concluding that the associated delay in computing shared savings payments is warranted by the increased accuracy of the underlying data used. CMS requests comments concerning additional considerations that would make the use of a three-month claims-run-out period more appropriate.

3. DATA SHARING

a. *Scope of the Proposed Regulations*

The Proposed Regulations recognize that access to appropriate data will be essential for an ACO to comply with the quality measurement and reporting requirements of Section 1899(b)(2)(A) of the ACA, but the ACA is silent regarding whether and to what extent CMS may or should provide ACOs with CMS data to assist them in meeting these requirements.²⁰ CMS states that ACOs eventually will be expected to "self-manage" independently their assigned beneficiary populations by identifying and producing the data they believe necessary to (a) monitor and evaluate the performance of their participants and providers/suppliers relative to quality and patient experience benchmarks, (b) produce efficiencies in the utilization of services, (c) conduct quality improvement activities, (d) evaluate the health needs of the populations they serve, (d) conduct population-based activities to improve the health of their populations and (e) improve health outcomes. Recognizing that many ACOs will be unable to meet that burden at the outset, the Proposed Regulations call for CMS to provide ACOs with three categories of information, including two types of beneficiary-identifiable data and aggregated data reports that will contain none of the HIPAA identifiers.²¹ CMS notes that combining the CMS-provided data with provider level and other data internally

generated and compiled within the ACO will enable an ACO to develop a more complete picture of the care that its beneficiary population receives within and outside the ACO of its participants' and providers' patterns of care, as well as to compare the ACO's current year performance with that of the previous year.

The Proposed Regulations describe the types of data CMS would share, articulate the rationale for proposing to make the CMS data available, and summarize the analysis underlying CMS's determination that sharing the data with ACOs is legally permissible under the ACA, HIPAA and other applicable federal privacy laws. The Proposed Regulations also adopt a "belt and suspenders" approach to managing the privacy risks, by imposing certain additional privacy protections that go beyond what federal privacy laws would require.

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- ☑ Notably, the Proposed Regulations' data-sharing provisions focus on the sharing of data by CMS with ACOs, not data-sharing within an ACO and among its participants and providers/suppliers, and, therefore they do not identify or analyze federal or state law restrictions that would limit such internal data-sharing.

b. Types of Data Sharing and Underlying CMS Rationale

I. FOUR SPECIFIC BENEFICIARY-IDENTIFIABLE DATA ELEMENTS

If requested by an ACO, CMS would provide the ACO with four data elements at the beginning of the first performance year of its agreement—name, date of birth, sex and Health Insurance Claim Number (HICN)—for beneficiaries who historically received the plurality of primary care services from the ACO's primary care physician participants. Having these data elements will enable the ACO to identify the beneficiaries CMS used to generate the aggregate reports (described below) and to determine the ACO's benchmark.

CMS recognized certain risks inherent in disclosing beneficiary-identifiable data on a historical basis,²² but concluded that the risks are outweighed by the potential benefits of knowing this information, such as the ability to identify needed improvements in care processes and coordination strategies (e.g., assuring timely access to office-based or clinic-based care to avoid unnecessary emergency room visits, improved care coordination strategies).²³ The Proposed Regulations also include certain other provisions to protect against that risk and allow CMS to achieve the intended benefits. Beneficiaries would not be given the right to *opt out* of having CMS share these data elements with their ACOs.

II. BENEFICIARY-IDENTIFIABLE CLAIMS DATA

ACOs would be able to request identifiable CMS claims data on a monthly basis for the beneficiaries who have received services from the ACO participants and providers/suppliers during the performance year. Subject to certain limitations described below, CMS would provide the data in the form of a standardized data set that includes the *minimum necessary*²⁴ data to assist the ACO in evaluating the performance of its participants and providers/suppliers, conducting quality assessment and improvement activities, and conducting population-based activities relating to improving the health of the ACO beneficiary population.

An ACO may choose to make its request for the claims data either as part of the application process or during its three-year agreement period. In either case, the ACO must submit a formal request that explains how it intends to use the data in evaluating the performance of its participants and providers/suppliers. The ACO must also attest that it is either a HIPAA-covered entity or a business associate of the ACO's participants and providers/suppliers (which themselves are HIPAA-covered entities), that the ACO is requesting only the minimum data necessary for those permitted MSSP purposes and that the ACO will limit its use of the data to the MSSP permitted purposes. As a business associate, the ACO must further attest that its business associate agreements authorize it to request the claims information for the permitted purposes described above; as a covered entity, the ACO must further attest that it is requesting the claims data only for its own patients.

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- ☑ An ACO and its providers and suppliers may find it helpful to have historical beneficiary-identifiable data and aggregated data reports prior to and during the application process to analyze and assess the financial feasibility of participation in the MSSP and to begin to develop the ACO's quality, care coordination, patient experience and cost efficiency strategies. However, the Proposed Regulations call for CMS to share such data only during the three-year agreement period.

The Proposed Regulations impose certain limitations and conditions on the sharing of the CMS beneficiary-identifiable claims data that go beyond what HIPAA would require,²⁵ and expressly recognize specific disclosure prohibitions and restrictions imposed under applicable federal law. First, as part of the overall ACO communication plan envisioned by the Proposed Regulations, 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 their participation in the MSSP and the potential for CMS to share their identifiable data with the ACO. The ACO must also provide beneficiaries with notice of their opportunity to opt out of having their CMS claims data shared with the ACO and with a form to use in exercising the opt out.²⁶ The ACO may not request data on beneficiaries who have exercised their opt out right. CMS will maintain a list of HICNs that have elected to opt out.

Second, the ACO must enter into a Data Use Agreement (DUA) prior to receiving any data, under which the ACO would agree to comply with the limitations and requirements of HIPAA and other applicable privacy and confidentiality requirements, as well as to use and disclose the data only in the manner that a HIPAA-covered entity may use and disclose it, and not for any prohibited purpose.²⁷ The DUA would also expressly provide that failure to comply with the DUA would render the ACO ineligible to continue to receive the data and could lead to imposition of sanctions and penalties available under applicable law as well termination of its agreement.

Third, absent express consent from the beneficiary, CMS will not share claims data from records maintained in connection with federally conducted or assisted substance abuse programs that reveals a beneficiary's identity, diagnosis, prognosis or treatment.²⁸

The Proposed Regulations state that "[t]he decision to opt-out in no way effects use of the beneficiaries' data or assignment to the ACO for purposes of determining such calculations as ACO benchmarks, per capita costs, quality performance or performance year per capita expenditures."

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- ☑ Arguably, these provisions are intended to allow CMS to continue to use the identifiable data to conduct analysis, provide aggregated data reports, and set performance benchmarks and standards. Nonetheless, the statement is vague and needs clarification concerning the scope of permitted disclosure and use of claims data regarding beneficiaries who have elected to opt out.

A further condition on an ACO's right to request and receive the data from CMS is that the "ACO does not [impose] unnecessary limitation or restrictions on the use or disclosure of individually identifiable health information that it internally compiles from providers and suppliers both within and outside of the ACO."

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- ☑ On its face, this condition is vague, and CMS provides no discussion or explanation of its intent and scope.

CMS acknowledges the importance of providing beneficiary-identifiable claims data that is both current and timely for an ACO to be able to establish baselines of utilization and patient morbidity, identify key beneficiaries and subpopulations for proactive care coordination efforts, and track its progress against defined performance measures.²⁹ Therefore, CMS proposes to provide the claims data on a *monthly basis* during the current performance year, instead of providing prior year historical data. CMS notes, however, that this claims data will not provide the basis for either (a) "real time" responses to the ACO's providers during a beneficiary's hospital stay (because of the "claims lag" between the time of discharge and the hospital's submission of the claim to CMS) or (b) a full analysis of the beneficiary population that the ACO cared for during the

performance year (because the ACO's beneficiaries are free to choose to obtain services from providers outside the ACO). Accordingly, CMS encourages ACOs to pursue access to more timely and complete beneficiary-identifiable claims data through other means and sources, such as through the implementation of interoperable health records, participation in health information exchanges, and more effective coordination with admission and discharge personnel in hospitals utilized by the ACO's patients. These other data strategies will also position the ACO to identify and produce the data that it will need to "self-manage" its assigned beneficiary populations, a capability that CMS will come to expect of the ACO.

III. AGGREGATED DATA REPORTS

CMS would provide aggregated data reports containing metrics on the assigned beneficiary population and beneficiary utilization data at the start of the agreement and quarterly aggregated data reports thereafter based on the most recent 12 months of assigned beneficiary data. The data will not include beneficiary-identifying information.³⁰ Instead, CMS will include de-identified claims history of the services rendered for the ACO's beneficiaries. This data would be intended to help ACOs to achieve the primary goals of improving the quality of care, improving the health of their assigned populations and creating efficiencies. Possible uses identified in the Proposed Regulations include (a) monitoring, understanding and managing an ACO's utilization and expenditure patterns, and (b) developing, targeting and implementing quality improvement programs and initiatives.

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- ☑ The Proposed Regulations do not describe in detail the nature and content of the reports that CMS would provide to an ACO or indicate whether they will be similar to those provided under the PGP Demonstration. The Proposed Regulations simply state that the reports will include information on financial performance, quality performance scores, aggregated beneficiary population metrics and beneficiary utilization data. Insights on what it is likely to include can be drawn from the somewhat detailed description of the annual profile report it provided to participating group practices in the PGP Demonstration, which also included information on financial performance,³¹ quality performance,³² aggregated beneficiary population metrics³³ and certain beneficiary encounter data.³⁴

4. LEGAL AUTHORITY FOR CMS SHARING OF BENEFICIARY-IDENTIFIABLE DATA

Section 1106 of the Social Security Act generally bars the disclosure of information collected under the Affordable Care Act without beneficiary consent, unless otherwise permitted by applicable statutes and regulations. The Proposed Regulations rely primarily on the HIPAA Privacy Rule³⁵ as support for the permissibility of sharing with ACOs the four beneficiary-identifiable data elements and the beneficiary-identifiable CMS claims data. The Proposed Regulations also recognize and discuss the provisions of (a) federal law governing disclosure of information from records created in connection with federally conducted or assisted substance abuse programs;³⁶ (b) the Federal Privacy Act that generally prohibits disclosure of information from a system of records by agencies such as CMS to any third party without the prior written consent of the individual to whom the records apply;³⁷ and (c) the special rule issued in May 2008 authorizing the Secretary to collect Part D claims data originally collected for Part D payment purposes for use in research, analysis, reporting and public health functions.³⁸ In short, the Proposed Regulations conclude that the proposed data-sharing under all these federal statutes, regulations and rules is permissible, and therefore that an ACO may request CMS to share the data for beneficiaries that have not chosen to opt-out, so long as the ACO has complied with the DUA, attestation and other requirements specifically imposed under the Proposed Regulations.

a. *HIPAA Compliance*

The MSSP is part of the Medicare FFS Program, which is a health plan and a "covered entity" subject to HIPAA. The ACO's participants and providers/suppliers are also HIPAA-covered entities. The ACO would be a covered entity if it is a provider of health care services and engages in HIPAA-covered electronic transactions. In other cases, the ACO will function as a business associate of the ACO participants and be permitted under HIPAA to receive and use identifiable information to carry out health care operations on their behalf. The ACO will use the beneficiary-identifiable information in activities that qualify as its own health care operations (if a provider) and the health care operations of its participants under the first and second paragraphs of the HIPAA definition of "health care operations."³⁹ Finally, CMS and the ACO (if a provider),

and CMS and each of the ACO's participants, have had a "relationship"⁴⁰ with the beneficiaries whose identifiable claims information is being shared, and the disclosure of the data by CMS pertains to that relationship.⁴¹ Accordingly, HIPAA permits an ACO to request CMS to disclose identifiable plan beneficiary data to the ACO and its participants, without obtaining an express authorization from the beneficiaries or qualifying for a waiver or exception to the HIPAA authorization requirement, so long as the information provided is only the minimum data necessary to accomplish the MSSP goals of the ACO.⁴²

b. Compliance with Federal Substance Abuse Program Records Laws

The Proposed Regulations take a broad-brush, conservative approach to compliance with federal laws applicable to disclosure of substance abuse program records. That is, CMS simply would not share claims data from records maintained in connection with federally conducted or assisted substance abuse programs that reveals a beneficiary's identity, diagnosis, prognosis or treatment absent an express authorization by the beneficiary.⁴³

c. Privacy Act Compliance

CMS concludes that the proposed sharing of beneficiary-identifiable data with ACOs is permitted under the Federal Privacy Act as a "routine use," because it would constitute disclosure to someone outside the agency that is compatible with the purpose for which CMS collected the data.

d. Part D Data Rule

The Proposed Regulations appear to conclude that the sharing of Part D data with an ACO is permissible under the final rule governing the re-collection and secondary use of Part D claims information, based on the following two statements made in the Proposed Regulations: (a) the intent of the rule is to allow use of the Part D data for a wide variety of purposes, including "supporting care coordination and disease management programs" and "supporting quality improvement performance measurement activities,"⁴⁴ and (b) "it is in the interest of public health to share the information collected . . . with entities outside of CMS for legitimate research . . ."⁴⁵

ACTION ITEM

- ☑ Development and implementation of an electronic health data strategy and supporting technology infrastructure are immediate and critical steps for any accountable care strategy—whether it involves participation in the MSSP as of January 12, 2012, or any time thereafter, other innovative payment models under ACA (e.g., bundled payments), or pay-for-performance and other payment innovations in the private sector. Accordingly, all stakeholders must move swiftly and deliberately to establish an electronic data strategy and supporting infrastructure. In doing so, it is important to recognize that there is no "one size fits all" or risk-free approach.
- ☑ Evaluate the capacity and capability of the current health information infrastructure to support robust quality measurement, analytics and reporting, care coordination and alignment of incentives under new payment and reimbursement models.
- ☑ Accelerate electronic health record (EHR) system implementation and integration in both the inpatient and ambulatory care settings. Take advantage of current flexibility under federal fraud and abuse laws to donate EHR technology to physicians; financial incentives available under the 2009 HITECH Act for meaningful use of certified EHR technology; and emerging health information exchange initiatives at community, regional and state-wide levels.
- ☑ Address the "build vs. buy" decisions early in the planning process, by taking the following actions, among others:
 - Exploring opportunities to supplement internal electronic data capabilities and infrastructure, at least for the short term, with "outsourced" and subscription-based capabilities such as third-party registry and quality/performance analytics and the rapidly evolving "cloud computing" service model paradigm
 - Anticipating and exploring opportunities to collaborate with other hospitals and health systems, state governments, universities and others to leverage human and capital resources and to reduce the learning curve

- ☑ At a minimum, an ACO should determine when and to what extent it will need CMS beneficiary-identifiable beneficiary information and claims data, as well as aggregated data reports, and should be ready to receive electronic CMS data and, over time, to aggregate CMS data with internally generated beneficiary and provider data.
- ☑ Consider the prospects under any data strategy for leveraging the infrastructure and resources to develop robust information repositories that will support innovations in the delivery of care (including personalized medicine) and payment mechanisms not only now but well into the future.
- ☑ Analyze the federal and state privacy and security law risks of sharing between and among ACO participants of identifiable data that is either provided by CMS or internally generated within the ACO.
- ☑ Determine whether the ACO will need the beneficiary-identifiable data and aggregated data reports CMS is willing to provide, and whether the ACO will make the request for the data at the time it files the MSSP application or during the three-year period of the MSSP agreement. If the ACO will make the request in the application, begin to prepare the explanation of how it intends to use the data.
- ☑ Prepare the signage and written notices needed to explain to beneficiaries the possibility that CMS may share their identifiable information with the ACO, and the form a beneficiary can use to exercise his or her information-sharing opt-out right. To be meaningful, an opportunity to opt out must (a) be provided with enough advance notice to make the opt-out decision, (b) provide adequate information about how the information will be shared and used and the benefits and risks of making their data available for the proposed uses, (c) not be coercive, and (d) not permit the information to be used for discriminatory purposes. The opt-out form itself must include a phone number, facsimile number or e-mail address to make an affirmative request that the beneficiary's information not be shared.
- ☑ Adopt policies and procedures for complying with the CMS information-sharing notice and opt-out requirements (including, among other things, the means of tracking which beneficiaries have elected to opt out) and the DUA.

C. Assignment of Medicare Fee-For-Service Beneficiaries

Section 3022 of the ACA requires the Secretary to “determine an appropriate method to assign Medicare FFS beneficiaries to an ACO based on utilization of primary care services provided” by ACO professionals who are physicians. To determine such a methodology it is necessary to establish (a) an operational definition of an ACO for beneficiary assignment purposes, (b) a definition of “primary care services,” (c) whether beneficiaries will be assigned to an ACO prospectively or retrospectively, and (d) the portion of primary care services that must be rendered by an ACO to a beneficiary in order to assign such beneficiary to the ACO.

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- ☑ The beneficiary assignment rules highlight the tension between beneficiary freedom of choice, which is guaranteed by the statute, and the desire for greater “accountability.” The resulting compromise will prove a major challenge to ACOs. The end result is an attempt to hold ACOs “accountable” for the care they provide to a specific population of Medicare FFS beneficiaries, even though (a) the ACO will not know at any point which beneficiaries are currently in the ACO, (b) the ACO can exert no control or influence over which providers the “assigned” beneficiaries use (i.e., there is no control over the use of non-ACO providers by assigned beneficiaries), and (c) the ACO may not even receive information regarding services provided to “assigned” beneficiaries by non-ACO providers if the beneficiary “opts out” of information sharing. These rules present material obstacles in the quest for higher quality and more efficient (i.e., more “accountable”) health care for Medicare FFS beneficiaries.

1. DEFINITION OF ACO FOR PURPOSES OF BENEFICIARY ASSIGNMENT

As noted above, CMS proposes to define an ACO, for purposes of beneficiary assignment, as a group of Medicare-enrolled providers identified by TINs. While CMS considered defining an ACO, at least in part, based on National Provider Identifiers (NPIs), CMS concluded that TINs are more stable than NPIs and, therefore, more likely to provide meaningful longitudinal data required for benchmarking and beneficiary assignment, and to promote stability in ACO make-up.

The Proposed Regulations would also require ACOs to report the NPIs for all associated ACO professionals for quality reporting purposes required under the legislation, including under the MSSP.

The Proposed Regulations require that primary care physicians (defined as internal medicine, geriatric medicine, family practice and general practice physicians) be exclusive to a single ACO, though they may participate in other non-ACO integrated entities. Specialists, on the other hand, may have relationships with more than one ACO.

2. DEFINITION OF PRIMARY CARE SERVICES

The Proposed Regulations discuss three potential approaches to defining “primary care services” for purposes of beneficiary assignment. The first approach is assignment based on a defined set of “services,” *e.g.*, certain evaluation and management services, regardless of the type of provider furnishing such services. The second approach is assignment based on a defined set of “services,” but only to the extent such services are provided by appropriate primary care providers. The third approach is a two-step approach, where the first step is the second approach summarized above, and the second step is to include within the calculation primary care services provided by a specialist, but only where such services are delivered to a patient who is not seeing a primary care physician. The Proposed Regulations adopt the second approach, while acknowledging that this approach might not adequately account for primary care services that are increasingly delivered by specialists to Medicare beneficiaries, which could, in turn, reduce the number of beneficiaries assigned to an ACO, especially in areas with a shortage of primary care physicians but a relatively greater number of specialists.

3. PROSPECTIVE VERSUS RETROSPECTIVE BENEFICIARY ASSIGNMENT

CMS estimates that beneficiary assignment to ACOs could change by approximately 25 percent each year. This makes the choice between prospective and retrospective assignment of beneficiaries to ACOs an important one. On the one hand, while being “accountable” for the care provided to a defined population would suggest the necessity of defining that population prospectively, as a result of the statutory protection of a beneficiary’s freedom of choice of provider, as a practical matter prospective assignment would result in an ACO being accountable for a substantial amount of care that its participants and other providers did not deliver. On the other hand, under a system of retrospective assignment, an ACO will not know in real time the patient population for which it is accountable.

The Proposed Regulations adopt the approach of retrospective beneficiary assignment for purposes of determining eligibility for shared savings. In order to offset some of the negative consequences of such an approach, however, the Proposed Regulations also call for the provision of aggregate beneficiary level data to an ACO for the population of Medicare beneficiaries that would have been assigned to the ACO, under the assignment rules, during the benchmark period. CMS believes this approach will give ACOs the information they need, while incentivizing them to improve the care provided to all beneficiaries, because ACOs will not know the exact population for which they are accountable.

4. MAJORITY VERSUS PLURALITY RULE FOR BENEFICIARY ASSIGNMENT

The Proposed Regulations consider whether beneficiaries should be assigned to an ACO only if they receive a majority of their primary care services from the ACO, or, alternatively, whether an ACO assignment should be made based on a plurality rule (*i.e.*, the ACO primary care physician who delivered more primary care services to the beneficiary than any other ACO primary care physician). The Proposed Regulations adopt the plurality approach and define the quantity of primary care services based on allowed charges. The Proposed Regulations invite comments on whether there should be a minimum threshold in applying the plurality rule.

5. BENEFICIARY INFORMATION AND NOTIFICATION

The Proposed Regulations acknowledge that the ACA is silent as to whether beneficiaries should be informed in any way about the MSSP. CMS concludes, however, that exercise of free choice in providers by beneficiaries could be “undermined or even nullified” if beneficiaries are not sufficiently informed about the MSSP and ACO assignment. While the choice of retrospective assignment of beneficiaries to an ACO means that no beneficiary can be informed prospectively of his or her assignment to an ACO, CMS states its view that some form of notice about the MSSP is required. Specifically, the Proposed Regulations require ACOs to (a) post signs in ACO facilities indicating their participation in the MSSP, (b) make available standard written materials developed by CMS, and (c) supply a “form” allowing beneficiaries to opt out of having their data shared.

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- ☑ It is not clear from the Proposed Regulations how and whether primary care services delivered by providers with no ACO affiliation will be aggregated. For example, if a beneficiary receives 40 percent of his or her primary care services from an ACO primary care physician and 60 percent of his or her primary care services from a collection of non-ACO-affiliated providers, with no single provider representing more than 10 percent of the total, would that beneficiary be assigned to the ACO?
- ☑ It is not clear how the “opt-out” would work. By using the term “form,” and requiring the ACO to provide the beneficiary with that “form,” the Proposed Regulations suggest that ACOs would have to provide a form that a beneficiary could sign to opt out of data sharing. However, the Proposed Regulations go on to state that the “form” must include a phone number, fax or e-mail address for beneficiaries to contact and request that their data not be shared. This description suggests a “notice” rather than a “form.” Obviously, the ease with which a beneficiary can “opt out” could affect the percentage of beneficiaries choosing to do so, which could in turn have a material impact on the ability of ACOs to meet the stated goals of the MSSP.
- ☑ For those organizations planning to start an ACO, perhaps the most important practical impact of the beneficiary assignment provisions of the Proposed Regulations is that primary care physicians must be exclusive to a single ACO. Moreover, primary care physicians signing up with an ACO will be committed to that ACO for the three-year period of the initial ACO agreements. The shortage of primary care physicians is well documented. These rules could increase the already intense pressure on hospitals and health systems to establish greater “alignment” with primary care physicians. Those health systems and other organizations hoping to become ACOs that do not act quickly to align with primary care physicians may have difficulty finding an adequate pool of primary care physicians for the ACO.

D. Quality and Other Reporting Requirements

1. INTRODUCTION

CMS has proposed measures to assess the quality of care furnished by an ACO, consistent with CMS’s aim to tie payment to value and to reward better patient outcomes rather than volume. Assessment of quality measures would occur over a three-year span, with the performance standards defined by the reporting level during the first year of the MSSP, with measure scores used as a guide in subsequent years. In addition, CMS is seeking to adjust for risk and differences in patient population and provider characteristics; achieve alignment with Medicare and Medicaid reporting and payment systems; and minimize the burden of reporting by aligning methods and measures with EHR incentive programs and existing standards, and by obtaining endorsement of the measures by a multi-stakeholder organization. Scoring on the measures will be based on overall achievement relative to national and other benchmarks, with improvement in measures as an overriding goal. Over time, it is anticipated that the scoring methodologies will be weighted to favor outcomes, patient experience and functional status. To make them fully functional, scoring methodologies will focus on measures of success in a manner that makes them reliable, straightforward and stable over time, thereby providing a mechanism for stakeholders to truly evaluate provider performance.

2. PROPOSED MEASURES TO ASSESS THE QUALITY OF CARE FURNISHED BY AN ACO

The proposed quality measures are prioritized to address the articulated goals of achieving better care for individuals and better health for populations by addressing a broad spectrum of quality domains that incorporate concepts from the Institute of Medicine and the National Quality Strategy, as well as other priority areas (such as cardiovascular disease), and support the goals of the MSSP. The measures also strive to align with existing (and likely future) Medicare incentive programs, such as the Physician Quality Reporting System (PQRS) measures, Electronic Prescribing Incentive Program, EHR incentive programs, Hospital Inpatient Quality Reporting Program, and Medicaid and public-sector initiatives. As such, the measures set forth in the Proposed Regulations overlap with existing measures that are often collected for other health care program reporting purposes.

ACO participants will need to establish their quality performance in the first year of the measuring period (Year One) by fully reporting their performance against 65 measures, organized into five “domains.” In Year One, meeting the standards would require “full and accurate” reporting of measures. Year One reports will be based on claims data. In subsequent years, the ACO’s compliance would be based on whether the ACO actually reaches identified performance thresholds. The measures that reflect established standards are noted to need modification in order to be applicable to ACOs. As noted above, the Proposed Regulations would require ACOs to meet standards in all three years in order to meet the quality performance standards sufficiently to qualify for shared savings.

The five “domains” and their measures include the following:

- *Patient/Caregiver Experience* – Seven measures focus on consumer assessment of health care providers and systems. These measures are aligned with National Quality Forum (NQF) endorsed standards.
- *Care Coordination* – Sixteen measures address clinical data, such as admissions and readmissions for specific disease processes, medication reconciliation, information services measures such as HITECH compliance, and meaningful use participation. These measures reflect CMS program measures and NQF endorsed standards.
- *Patient Safety* – Two measures focus on health care acquired conditions, including Agency for Healthcare Research and Quality (AHRQ) patient safety indicators (PSIs). These measures are aligned with CMS programs on health care acquired conditions and NQF endorsed standards.
- *Preventive Health* – Nine measures address common preventive services, including immunization, disease and health screening, and measurement and management of health conditions. These measures reflect PQRS measures, EHR incentive programs and NQF standards.
- *At-Risk Population/Frail Elderly Health* – Thirty-one measures focus on specific measures for diabetes care, heart failure care and treatment, coronary artery disease treatment, hypertension control and care planning, chronic obstructive pulmonary disease screening, counseling and treatment, and screening and management of health care concerns of particular relevance to the frail elderly population. These measures are aligned with NQF standards, EHR incentive programs, PQRS standards and CMS programs.

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- ☑ Notably, as the proposed measures apply only to Year One, quality measures for the remaining two years will be generated through future CMS rulemaking. It is anticipated that the measures will broaden in scope and focus over time, and expand to include hospital-specific quality measures and measures for other health care settings, including nursing homes.

3. REQUIREMENTS FOR QUALITY MEASURES DATA SUBMISSION BY ACOS

Reporting of results will be made via claims reporting through a newly developed, electronic-database-driven ACO Group Practice Reporting Option tool (ACO GPRO), based on the current reporting tool utilized in the PQRS group practice reporting option and PGP Demonstration. This will require the existing tool to be substantially refined. The refined ACO GPRO tool will rely on sampling methodology similar to that utilized in the 2011 PQRS GPRO reporting process, with a minimum of 411 beneficiaries in a sample per domain measured (or the total number of beneficiaries, if less than 411). For certain measures, an ACO will be asked to report by attestation rather than by sampling (for example, measures in the Care Coordination domain addressing meaningful use participation and EHR incentive participation). In addition, survey instruments may also be utilized for reporting other measures.

The ACO GPRO tool is intended to interface with EHR technology, to eventually permit the tool to be electronically populated with the required quality data. While alignment of the programs will entail additional rulemaking, the use of EHR for data reporting purposes is anticipated in future program years.

Data submitted by ACOs is subject to validation. Auditing of data would be conducted with a sample of 30 beneficiaries whose care had been abstracted to create data reports (*i.e.*, 30 of a sample of 411). Starting with a subset of eight of the 30 records (Phase I Review), the records will be reviewed for mismatched data. If the Phase I audit identifies no issues, the audit stops and the remaining 22 records would not be reviewed. If mismatches are identified during the Phase I audit, the audit advances to the next phase (Phase II) at which point the remaining 22 records would be reviewed. If greater than 10 percent of the records in Phase II have mismatches, the audit advances to the final phase (Phase III). If the error rate remains at greater than 10 percent after Phase III, the ACO would not be given credit for meeting the target for that measure and corrective action would be taken against the ACO participant. This corrective action could include education and an opportunity to correct the error and resubmit data for the measure at issue. Failure to report data accurately, completely and in a timely manner may result in the ACO being terminated from the MSSP or other sanctions, as described below.

An ACO that fails to meet the quality performance thresholds for all proposed measures would be ineligible to receive shared savings, regardless of the success of the ACO in reducing costs. The ACO would be disqualified from sharing in savings for each year it fails to meet measures. However, failure to meet a minimum attainment level in one “domain” does not instantly exclude an ACO from participation during the entire performance period. The Proposed Regulations provide that failure to meet one or more measures will result in communication with the ACO and re-evaluation the following year. If the ACO fails to comply the following year after the warning, the ACO’s participation agreement will be terminated. ACOs may also be terminated from the MSSP for failure to provide data reports or to respond to ACO correspondence requesting information or an explanation for delays.

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- ☑ As the performance measures are identified for only Year One, the measure refinement for the subsequent second and third years of the reporting period are unknown to an ACO at the start. Since shared savings can only be achieved after compliance for three years, ACOs are being asked to participate with part of the MSSP rules yet unknown.
- ☑ Data collection may be a burden for ACOs. While there is a significant overlap in measures with those that are already collected by many facilities for other quality reasons, for those who do not report or have not consistently reported in the past, or who do not have the manpower to prepare the data, reporting compliance could be a challenge.
- ☑ The need to modify the GPRO tool in time for a 2012 rollout seems uncertain. The other mechanisms for reporting (surveys and attestations) are not fully developed.

4. QUALITY PERFORMANCE STANDARDS

a. *Measuring Quality Performance*

As discussed above, CMS has proposed 65 measures, subdivided into five overarching domains. These measures will be used to establish the quality performance thresholds ACOs must meet in order to be eligible for shared savings under the MSSP. The domains and their respective measures are listed below. CMS has organized the quality performance measures in Domains 2 and 5 into several categories that group similar measures. (See Exhibit A for details.)

b. *Methods For Establishing Quality*

The data gathered from the 65 measures listed above will be used to calculate an ACO’s quality performance standard, and thereby its quality of care. For the first year of an ACO contract, CMS defines the quality performance standard as “complete and accurate reporting” of an ACO’s performance on the 65 measures.⁴⁶ Data based on the 65 measures will be used to determine the quality performance standard for subsequent performance years. CMS has proposed two options of calculating the quality performance standard: Performance Scoring and Quality Threshold. Performance Scoring will reward an ACO with a larger shared savings percentage if it demonstrates better quality. Quality Threshold will give an ACO its full shared savings percentage if it meets a minimum standard of care. CMS proposes the Performance Scoring option and seeks comments on Quality Threshold.

c. *Performance Scoring*

Under the proposed Performance Scoring option, an ACO will be given a total performance score that is derived from a formula using the 65 measures. ACOs with a higher total performance score, and therefore a higher quality of care according to CMS, will receive a larger percentage of shared savings.

In general, the measures under each domain are first individually scored. Next, these scores will be summed to calculate a total score for each respective domain. The scores for each of the five domains are then aggregated using the weighting method previously described. This weighting process strives to treat all domains equally, avoiding placing more value on some aspects of patient care than others. The aggregated number, which shall be the ACO’s total performance score, determines the ACO’s quality sharing rate. The ACO’s quality sharing rate will, in turn, be used to calculate the ACO’s shared savings. The ACO will be eligible to share up to 50 percent of the total savings it creates under the one-sided risk model, and up to 60 percent of the total savings it realizes under the two-sided risk model.⁴⁷

CMS will determine a “performance benchmark”⁴⁸ and a “minimum attainment level”⁴⁹ for each measure based on the Medicare FFS Program, Medicare Advantage and ACO performance data.⁵⁰ Prior to the start of each performance period, CMS will release the benchmark levels to ACOs. After the first year of the MSSP, it is expected that the benchmark numbers will be adjusted based on actual ACO performance. CMS may also increase the benchmark thresholds in subsequent years, in order to motivate ACOs to improve the quality of care they provide.

An ACO may earn points for each of the 65 measures. According to the performance level attained by the ACO, it will earn up to two points for each measure.⁵¹ The applicable sliding scale performance levels and their corresponding quality points are in the chart below:

TABLE 1: SLIDING SCALE OF AVAILABLE QUALITY POINTS

ACO Performance Level	Quality Points
90+ percentile FFS/MA Rate or 90+ percent	2 (the maximum possible points for a measure)
80+ percentile FFS/MA Rate or 80+ percent	1.85
70+ percentile FFS/MA Rate or 70+ percent	1.7
60+ percentile FFS/MA Rate or 60+ percent	1.55
50+ percentile FFS/MA Rate or 50+ percent	1.4
40+ percentile FFS/MA Rate or 40+ percent	1.25
30+ percentile FFS/MA Rate or 30+ percent	1.10
<30+ percentile FFS/MA Rate or <30+ percent	0

Under this approach, a calculated performance level below the minimum attainment level will earn zero points. Performance equal to or greater than the minimum attainment level, but still falling below the performance benchmark, will receive points on the sliding scale illustrated in the chart above. If the performance benchmark is met, the ACO will receive a maximum of two quality points.

There are two ways for an ACO to earn quality points for the diabetes and coronary artery disease categories in the fifth domain: (a) an “all or nothing” scoring method and (b) a sliding scale method. Two of the measures in the fifth domain, Diabetes Composite and Coronary Artery Disease (CAD) Composite, will be scored using an “all or nothing” approach. Under this approach, an ACO will receive the maximum available points only if *all* criteria are met; otherwise, no points will be awarded for these measures. The Diabetes Composite and CAD Composites are composed of all the Diabetes and CAD measures below them, respectively. If all of the measures are not completed, zero points will be awarded for the Composite, even if all of the criteria except one are fulfilled. As CMS explains, this “all or nothing” scoring method “is a signal to providers that failing to perform any element of a process is unacceptable” and will “provide greater insight into the use of these methodologies [and] drive ACOs to aggressively improve their population’s health.”⁵²

Since not all patients will require every type of care necessary to earn quality points for a Composite measure, CMS has proposed that an ACO can still earn points for the other Diabetes and CAD measures without getting credit for the Composite. For instance, if a patient underwent treatment that fulfilled four CAD measures, the ACO would not earn any points for the CAD Composite measure. The ACO would, however, receive points for the four measures that were applicable to the patient’s treatment. Another measure, Hospital-Acquired Conditions in Domain 3: Patient Safety, is also a Composite. Because the hospital-acquired conditions included in this measure are rare, this Composite is not scored under an “all or nothing approach” like the Diabetes and CAD composites. Instead, all of the hospital-acquired conditions have been grouped into one measure.

In addition to setting quality benchmarks for each individual measure for the first year of the MSSP, CMS will do the same for each domain. At the conclusion of a performance year, CMS will tally the number of points earned by an ACO for a particular domain and divide that number by the total number of points available for that domain in order to determine the ACO’s percentage for each domain; then the five domain scores will be used to formulate a total performance score for the ACO. The following chart⁵³ illustrates the total number of points available for each domain under both the one- and two-sided risk models. Each measure is worth a maximum two points. Note that the total number of points available as well as the points awarded for each domain are identical under both risk models. The only difference is in the potential shared savings received by the ACO.

TABLE 2: NUMBER OF QUALITY POINTS AVAILABLE FOR EACH DOMAIN

Domain	Total Number of Measures in Domain	Total Number of Potential Points Under the One-Sided Risk Model	Total Number of Potential Points Under the Two-Sided Risk Model
Patient/Caregiver Experience	7	14	14
Care Coordination	16	32	32
Patient Safety	2	4	4
Preventive Health	9	18	18
At-Risk Population/Frail Elderly Health	31	62	62
Total Quality Points Available	n/a	130	130
Total Potential Shared Savings	n/a	50 percent	60 percent

The ACO must score above the minimum attainment level for each measure in a domain in order for that domain to be eligible for shared savings. If the ACO meets the quality performance standards for one or more domains and also the requirements for generating shared savings, the ACO may receive shared savings. In order to receive its shared savings amount, it is vital that the ACO submit complete, accurate and timely reports about all of the quality measures. CMS may also audit the ACO's data. To illustrate, the Preventive Health Domain has nine measures and is therefore worth a total of 18 points.⁵⁴ The sliding scale illustrated in Table One will be used to determine exactly how many of these 18 available points the ACO has earned. If the ACO earns 16.2 points, it has earned 90 percent of the available points for the Preventive Health Domain.⁵⁵ If the ACO receives a 90 percent score for all five domains and realizes shared savings, under the one-sided risk model it will receive 45 percent of the total savings.⁵⁶ Following a similar process, under the two-sided risk model the ACO will receive 54 percent.⁵⁷

d. *Quality Threshold*

An alternative option that CMS has considered and is seeking comment on is a Quality Threshold. This approach would allow full shared savings (either 50 or 60 percent, depending on the risk model) if an ACO meets a minimum quality threshold determined by CMS.

CMS has suggested determining the minimum quality threshold with the same 65 measures used for the Performance Scoring method. The minimum quality threshold of performance for each domain will be the 50th percentile, calculated from the points method used for Performance Scoring and the sliding scale in Table One. If an ACO meets or exceeds the 50th percentile for each of the five domains, it would be eligible for the full amount of shared savings. If the ACO performs below the 50th percentile for any of the five domains, it would not receive any shared savings. As with the Performance Scoring benchmarks, CMS intends to raise the minimum quality threshold over time.

In contrast to the Performance Scoring option, in which an ACO can still be eligible for shared savings if it has very high quality for some domains and lower quality in others, under the Quality Threshold method the ACO would need to reach a certain level in all five domains in order to receive shared savings. In other words, unlike Performance Scoring, a Quality Threshold approach would not absorb poor quality outcomes due to random variability instead of truly inadequate care. CMS has a concern that once the ACO reaches the 50th percentile under the Quality Threshold method, the ACO would have no incentive to continue to improve care. Therefore, CMS favors the Performance Scoring option or a hybrid of the two methods.

5. INCORPORATION OF OTHER REPORTING REQUIREMENTS RELATED TO THE PQRS AND EHR TECHNOLOGY UNDER SECTION 1848 OF ACA

As discussed above, CMS proposes the creation of a PQRS GPRO under the MSSP. An ACO's eligible professionals⁵⁸ must be part of a group practice in order to qualify for the PQRS GPRO. Using the GPRO tool and methodology, group practices must submit information on the 65 quality measures in order to be considered for a performance bonus. To properly report data for the PQRS, the ACO must observe the following guidelines:

- The ACO, on behalf of its eligible professionals, will report on all of the measures included in the GPRO data collection tool.
- The GPRO data collection tool must be completed for all of the 65 quality measures and their respective domains.
- The ACO will need to complete the GPRO tool for the "first 411 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each domain, measure set or individual measure if a separate denominator is required such as in the case of preventive care measures which may be specific to one sex."⁵⁹ If the set contains fewer than 411 beneficiaries, the ACO must complete the tool for all of them.

If an ACO properly reports on the 65 quality metrics, its eligible professionals (as described in fn. 58) will qualify for a Physician Reporting System incentive under the MSSP. This incentive will be 0.5 percent of the eligible professionals' total estimated Medicare Part B Physician Fee Schedule allowed charges for covered professional services provided in the first year. No extra reporting is required in order to meet the requirements for both the MSSP and the PQRS. However, in order to be considered for both programs, the ACO must submit data on *all* 65 quality measures. If an ACO meets the quality thresholds for the MSSP, the ACO's professionals who are eligible for the PQRS may receive the 0.5 percent incentive. Conversely, if the ACO fails to reach the minimum levels under the MSSP, it will not receive shared savings and its

eligible professionals cannot get the PQRS bonus either. ACOs that meet the minimum quality standards but do not realize shared savings will still be eligible for the PQRS incentive. Finally, eligible professionals cannot double-qualify for the PQRS incentive as both a group and as an individual.

Successful performance in the EHR Incentive Program and the Electronic Prescribing Incentive Program will not yield incentive payments as described above. ACO professionals may still participate in these programs, although they will not be housed under the MSSP. The MSSP, however, has included measures related to EHR education. These measures do not overlap with the data gathered by the EHR Incentive Program and the Electronic Prescribing Incentive Program. In order for an ACO to maintain its eligibility for the MSSP in its second year, at least 50 percent of its primary care physicians must be deemed “meaningful EHR users.”⁶⁰

6. PUBLIC REPORTING

Several sections of the ACA are designed to increase the transparency of health care provided to Medicare beneficiaries.⁶¹ Although the ACA did not include the MSSP in these efforts, CMS has suggested public reporting for ACOs so they “become accountable for the quality, cost, and overall care”⁶² of their Medicare beneficiaries. Under the Proposed Regulations, ACOs must publicly report the following information:

- Name and location
- Primary contact
- Organizational information, including the following:
 - ACO participants
 - Identification of ACO participants in joint ventures between ACO professionals and hospitals
 - Identification of the ACO participant representatives on the ACO’s governing body
 - Associated committees and committee leadership
- Shared savings information, including the following:
 - Shared savings performance payments received by the ACO or shared losses payable to CMS
 - Total proportion of shared savings invested in infrastructure, redesigned care processes and other resources required to support the goals of better health for populations, better care for individuals and lower growth in expenditures, including the proportion distributed among ACO participants
- Quality performance standard scores

This data will be reported in a standardized format developed by CMS.

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- Currently, it is unclear where the information will actually be reported. It is also unknown whether ACOs themselves will make this information available to the public, or whether they will submit it to CMS, which will in turn release it.

7. ALIGNING ACO QUALITY MEASURES WITH OTHER LAWS AND REGULATIONS

The ACA requires the Secretary to develop methods to measure performance and award high quality for a variety of health care providers and programs. In an effort to organize these mandates, CMS has developed four domains, which are distinct from the domains used to organize the 65 measures previously discussed. (See Exhibit B for details.)

In addition to the proposed ACO regulations, CMS has already promulgated measurement tools for inpatient hospitals and Medicaid. Although the categories may overlap, each domain has distinct quality standards and metrics. CMS has suggested standardizing these domains for ease, so that to the extent possible, they utilize similar definitions and measurements.

E. Shared Savings Determinations

Section 3022(d)(1) of the ACA expressly provides for ACO participants to receive payment under Medicare FFS for every item or service the participants furnish to a Medicare beneficiary, regardless of whether the individual has been or would be assigned to the ACO.⁶³ Whether an ACO may share in the savings (or is required to share in the losses) it generates during any given performance year depends, in part, on whether the ACO (a) meets the minimum quality performance standards, and (b) generates more than the MSR required of the ACO in connection with its participation in the MSSP. If the answers to these questions are “yes,” then the next step is determining the amount of the savings the ACO may receive under the MSSP.

This section will discuss the key concepts that comprise the calculation of an ACO’s financial “benchmark,” MSR and “shared savings rate,” as well as other components of the shared savings calculation, before addressing some considerations that should be kept in mind regarding this payment methodology.

1. OVERVIEW OF THE ONE-SIDED AND TWO-SIDED FINANCIAL PERFORMANCE MODELS

CMS proposes to permit ACOs to select either an initially one-sided or entirely two-sided financial risk model for the first three-year agreement under the MSSP.

Under the initially one-sided model, the ACO would share in the potential “upside” savings generated in either of the first two performance years under the initial three-year agreement. In the third year (and any subsequent agreement term), however, the ACO would share in the potential “downside” risk as well, meaning the ACO would share with CMS any savings generated in the third performance year or, if losses were incurred, the ACO would be financially responsible for part of such losses. An ACO selecting the two-sided model would share with CMS the potential upside savings and downside risk for the entire term of the agreement.

Evaluating potential shared savings under either model involves a multi-step process:

- The ACO first must compare the financial results for a performance year to its benchmark amount, which CMS establishes at the beginning of the three-year term (and updates each year based on a pre-determined trend).
- Any savings achieved must exceed the applicable MSR (also determined by CMS) and, for certain one-sided model ACOs, 2 percent of the benchmark before the ACO may share the earned savings with CMS.
- For any savings in excess of the MSR, CMS would calculate the ACO’s portion of the savings according to the ACO’s “shared savings rate,” determined based on the ACO’s quality improvement rate and other available “add-ons.”
- In no event would the amount of shared savings for an ACO operating under the one-sided model exceed 7.5 percent of the ACO’s benchmark. (The amount increases to 10 percent for the third year of the agreement, when the initially one-sided ACO automatically converts to the two-sided model.)
- Of any shared savings due to an ACO for a performance year, 25 percent would be withheld by CMS until completion of the three-year term, as a reserve against potential future losses.

2. CALCULATING THE BENCHMARK FOR THE PERFORMANCE YEARS

The benchmark is perhaps the most critical element for defining an ACO’s potential financial opportunity under the MSSP. As CMS notes in the Proposed Regulations, “[a] useful way to view the benchmark is as a surrogate measure of what the Medicare FFS Parts A and B expenditures would otherwise have been in the absence of the ACO.”⁶⁴ An ACO’s benchmark

that is set inappropriately high would enhance the opportunity for the ACO to generate, and thus benefit from, achieved savings, while a benchmark set too low may artificially limit the ACO's ability to achieve savings.

The Proposed Regulations describe a five-step process for developing an ACO's unique benchmark, which would be based on historical cost data for the likely patient population, trended forward. The five steps include (a) determining the per capita expenditures for the likely patient population for each of the three years preceding the three-year term that would comprise the final benchmark (each of these three years to be considered a "benchmark year"); (b) developing a growth trend for the benchmark years; (c) incorporating adjustments for beneficiary characteristics that affect medical costs; (d) applying the growth trend and health status adjustments to the benchmark years; and (e) weighting the benchmark years to calculate the final benchmark amount, which would be trended forward for each performance year.⁶⁵

a. *Per Capita Expenditures*

CMS considered two approaches for estimating an ACO's benchmark, with one of the key differences between them being the method for selecting the patient population whose expenditures would provide the baseline Medicare costs. CMS proposes to adopt Option One, described below.

CMS proposes to use as the baseline for setting the benchmark the expenditures of those Medicare beneficiaries enrolled in Medicare FFS who would have been assigned to the ACO in each of the benchmark years.⁶⁶ The same "rules" for assigning individuals to an ACO to measure its performance for a given performance year would be used for selecting the patient population for the benchmark years. Therefore, CMS would pull the claims data for each TIN associated with the ACO, and then determine those individuals who received a "plurality" of allowed charges for primary care services from the ACO's participants in each of the three benchmark years.

For the benchmark population, CMS would calculate the "per capita expenditures" for Part A and B services based upon a retrospective examination that provides for a six-month claims run out. CMS also would "truncate" a beneficiary's total Part A and B costs at the 99th percentile of the final benchmark amount in order to minimize the potential cost variation that may result from catastrophically large claims. These per capita expenditures would be used to set initial amounts for each of the three benchmark years.⁶⁷

I. OTHER PAYMENT-RELATED ADJUSTMENTS

CMS is authorized by the law to adjust the benchmark for "other factors" the Secretary determines appropriate, in addition to the adjustment to reflect beneficiaries' characteristics described below.⁶⁸ According to CMS, the statute does not, however, authorize CMS to make corresponding adjustments when determining actual expenditures during a performance year, potentially creating a disparity between the two calculations that could affect the determination of savings. In contrast, CMS believes it may not include certain incentive payments in the calculation of expenditures for either the benchmark or performance years.⁶⁹ As a result, CMS elects to retain within the determination of expenditures for each of the benchmark years those payments that would also be reflected in the actual expenditures for the performance years, but to remove those incentive payments that are excluded from both equations.

a) *IME and DSH Payments Retained in Benchmark Calculation:* CMS proposes to include within the determination of per capita expenditures for each benchmark year the Medicare disproportionate share hospital (DSH) and indirect medical education (IME) payment adjustments. CMS states that both payment components must be included in the calculation of expenditures for each performance year, and therefore should not be removed from the calculation of the benchmark amount. CMS notes that retaining these incentive payments may increase the likelihood that certain types of hospitals, including academic medical centers, will choose to participate in ACOs (and would avoid any disincentive for ACOs to refer patients to these facilities that would be present if the payments were excluded from the benchmark calculation).⁷⁰

b) *Geographic Payment Adjustments Retained in Benchmark Calculation:* Geographic-based payment adjustments, such as the Inpatient Prospective Payment System (IPPS) wage index adjustment and physician fee schedule geographic practice cost index adjustments, also are retained for purposes of calculating expenditures for the benchmark and performance years.⁷¹

c) *Certain Bonus Payments and Penalties Excluded:* Medicare bonus payments (and penalties) that may be available to providers participating in certain value-based purchasing initiatives, such as the PQRS and the

electronic prescribing program (42 C.F.R. § 414.92), as well as the HITECH Act incentives for eligible professionals (42 C.F.R. § 495.102), would be excluded from the determination of expenditures for the benchmark years and performance years.⁷² Incentive payments authorized under other statutes, such as EHR payment to hospitals and critical access hospitals, respectively, would be included in the calculation of expenditures for the benchmark and performance years.⁷³

b. Accounting for Growth Trend

To trend the expenditures for each benchmark year forward to the start of the three-year term, CMS proposes to use the national growth rate for Part A and B expenditures for the Medicare FFS Program. Although CMS considered two options for the trending methodology—either a growth rate for Part A and B service expenditures or a flat dollar amount equivalent to the absolute amount of growth in per capita expenditures—CMS opted for the growth rate, which is perceived to be “relatively neutral and comparable” across geographic areas.⁷⁴ Furthermore, the national growth rate, rather than a local growth rate, was selected in order to “ensure that ACOs in both high spending, high growth and low spending, low growth areas will have appropriate incentives” to participate.⁷⁵

c. Adjustments for Beneficiary Characteristics

ACA requires modification of the benchmark to reflect beneficiary characteristics that are recognized as affecting medical costs. “This requirement to adjust for ‘beneficiary characteristics’ implicitly recognizes that . . . the realization of savings against a benchmark could be a function of two factors . . . greater quality and efficiency . . . [or] changes in the characteristics of the beneficiaries who are under the care of the ACO.”⁷⁶ CMS considered two options for accounting for beneficiaries’ characteristics—only demographic data (age, gender, Medicaid status, basis for Medicare eligibility, such as age-in or disability) or demographic and diagnostic data—ultimately selecting the latter. In making this selection, however, CMS acknowledges the concern of guarding against changes in a beneficiary’s risk score that reflect “more specific or comprehensive coding as opposed to improvements in the coordination and quality of care.”⁷⁷

To capture a beneficiary’s potential “risk score,” CMS proposes to use its Hierarchical Condition Category (CMS-HCC) risk adjustment model, which CMS currently uses under the Medicare Advantage Program. “In addition to demographic variables, the CMS-HCC prospective risk adjustment model uses beneficiaries’ prior year diagnoses to develop risk scores that are then applied to their current year expenditures.”⁷⁸ To protect against the potential incentive to increase risk scores (thus increasing the benchmark against which actual expenditures would be compared), CMS proposes to establish a single risk score for each ACO that would be applied to the benchmark years and to future updates to the benchmark itself. CMS anticipates that this approach of using the CMS-HCC model but limiting the effects of year-to-year coding improvements would allow for more accurate prediction of health care expenditures, and would also encourage ACOs to maintain complete and accurate medical documentation that may improve care coordination and quality improvement while countering incentives to achieve apparent savings by coding changes alone. (CMS also notes that it expects an ACO’s average population risk scores to be stable over time, both because there is expected to be some stability in ACO participants and patients and because the ACO’s risk score is calculated for the ACO’s historical assigned population, when there was no apparent incentive for providers to improve coding.)⁷⁹

The ACO’s benchmark risk score would be calculated by applying the CMS-HCC model to the historical beneficiary population assigned to the ACO for each benchmark year. Changes to the risk score among the performance years would not be included in the benchmark calculation, however.⁸⁰

d. Trending Forward – Risk- and Growth-Adjusted Benchmark Years

Once the preliminary per capita expenditures are calculated for each of the benchmark years, CMS proposes to combine these amounts with the respective growth index and risk score. The result would be the adjusted per capita expenditures for beneficiaries historically assigned to the ACO, stated in benchmark year three risk and dollar amounts (Adjusted Benchmark Amounts).⁸¹

e. Weighting the Benchmark Years

The final step in determining an ACO’s benchmark amount is weighting the Adjusted Benchmark Amounts to give greater emphasis to benchmark year three (more recent) expenditures as compared to benchmark years one and

two. CMS also notes that this weighting “allows us to establish lower MSRs since the weighting results in a more accurate benchmark.”⁸²

The Adjusted Benchmark Amount for benchmark year one would be weighted at 10 percent; the Adjusted Benchmark Amount for benchmark year two would be weighted at 30 percent; and the Adjusted Benchmark Amount for benchmark year three would be weighted at 60 percent.⁸³

f. Benchmark for Future Performance Years

CMS is required to update the benchmark amount for each performance year. The Agency proposes that the update—the projected absolute amount of growth in national per capita expenditures for Part A and Part B services under Original Medicare—be derived from actual claims and expenditures for Medicare beneficiaries.⁸⁴

g. Option Two – The Road Not Taken

CMS considered, but elected against proposing, an alternative methodology for selecting Medicare beneficiaries whose historical claims data would comprise the starting point for calculating per capita expenditures. Rather than pulling claims data for beneficiaries who would have been assigned to the ACO based on primary care services received in one of the benchmark years, Option Two would determine the benchmark based on Medicare beneficiaries *actually assigned* to the ACO. The benchmark would be re-calculated each year to account for newly assigned beneficiaries as well as previously assigned beneficiaries who no longer were assigned to the ACO in subsequent years (including, but not limited to, beneficiaries who died during the year).

For each of these individuals, CMS would calculate their respective per capita expenditures for Part A and Part B services during each of the three benchmark years. These amounts would be trended forward to the start of the term using the growth index and adjusted to reflect the beneficiaries’ health status, similar to CMS’s proposal under Option One.⁸⁵

3. MINIMUM SAVINGS RATE

An ACO’s savings must exceed the applicable MSR in order to be eligible to receive payment for shared savings under the MSSP. The MSR must “account for normal variation in expenditures . . . based upon the number of Medicare fee-for-service beneficiaries assigned to an ACO.”⁸⁶ As savings can occur as a result of normal variation in Medicare beneficiaries’ claims expenditures in addition to (or regardless of) an ACO’s activities, CMS is directed by the statute to impose a MSR that accounts for this variation. Ultimately, “[the] MSR in combination with the savings rate would determine the amount of shared savings that an ACO can receive.” A higher percentage MSR may result in an ACO’s performance more accurately reflecting the savings achieved through improved quality and efficiency. It also may result in fewer savings and could discourage potential ACO participants, particularly those new to the concept and smaller organizations. A lower MSR would offer greater potential financial rewards for ACOs but may undermine the potential accuracy of achieved savings.

CMS proposes to use “a sliding scale confidence interval” (CI) reflecting the number of assigned beneficiaries, to set each ACO’s MSR. Larger ACOs with a higher CI would be eligible for a lower MSR, while smaller ACOs would be assigned a higher MSR. In no instance would an ACO’s MSR fall below 2 percent (for ACOs with more than 60,000 attributed beneficiaries) or exceed 3.9 percent (for ACOs with the minimum of 5,000 beneficiaries).⁸⁷ If an ACO does not meet the applicable CI, that ACO may not receive any shared savings. Once the CI is met, the ACO is eligible for shared savings as discussed immediately below.

As an additional protection against ACOs participating in the one-sided model gaining a “windfall” in shared savings without the “initial accountability for losses and corresponding motivation to eliminate unnecessary expenses,” CMS is proposing an additional limitation on one-sided ACOs that achieve the MSR to sharing in savings only in that amount which is greater than 2 percent of the ACO’s benchmark.⁸⁸ An exemption would exist to permit first-dollar shared savings for ACOs that have fewer than 10,000 assigned beneficiaries (in the most recent year for which CMS has complete claims data) and meet at least one of the following criteria:

- All the ACO’s participants are physicians or physician groups.

- At least 75 percent of the ACO’s assigned Medicare beneficiaries reside in counties outside a Metropolitan Statistical Area.
- At least 50 percent of the ACO’s assigned beneficiaries were assigned on the basis of services received from Method II CAHs.
- At least 50 percent of the assigned beneficiaries had at least one encounter with a participating FQHC or RHC.⁸⁹

According to CMS, “This option would balance the need to have assurance that savings are not a result of random variation with the need to provide critical financial support for under-funded ACOs, particularly ACOs that serve a smaller population, safety net providers, or physician-only participants.”⁹⁰

4. SHARING RATE ADD-ONS

As an incentive to include FQHCs and RHCs, CMS proposes an “add on” to an ACO’s shared savings rate when these providers participate. As described in this paper, an ACO’s shared savings rate is based on its quality performance, and can be as high as 50 percent for ACOs initially under the one-sided model and 60 percent for ACOs under the two-sided model.⁹¹ A one-sided ACO may increase its shared savings rate based on the number of Medicare beneficiaries who have one or more visits at an FQHC or RHC during a performance year. The increase to an ACO’s shared savings rate would be calculated according to a sliding scale that links the increase shared savings rate to the percentage of assigned beneficiaries to visit an FQHC or RHC. The maximum available add-on would be 2.5 percent.

5. DETERMINING THE FINAL PAYMENT AMOUNT

a. *Performance Payment Limit*

Notwithstanding the potential savings that an ACO may generate, ACA requires CMS to “establish limits on the total amount of shared savings that may be paid to an ACO”⁹² Therefore, CMS proposes to cap one-sided ACOs, during the initial two years of their contracts, at 7.5 percent of their respective benchmark amounts. This limit is intended to strike a balance between providing ACOs with the opportunity to financially benefit from improving the quality and coordination and management of services, “while avoiding creating incentives for excessive reductions in utilization which could be harmful to beneficiaries.”⁹³

b. *Withholds*

One of the “sticks” CMS proposes to complement the “carrots” of shared savings with is a withhold from any earned shared savings payments. In addition to serving as an offset against potential future losses, the withhold also is intended to encourage ACOs to commit to the three-year agreement to participate in the MSSP. CMS proposes to withhold a flat 25 percent of any earned payment for a performance year.⁹⁴ At the end of each agreement period, any positive balances would be returned to the ACO, but the withheld monies would be forfeited if the ACO does not complete its three-year agreement.

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- ☑ The payment methodology CMS sets out in the Proposed Regulations is highly formulaic and data driven, leaving no real room for CMS to modify the payments for an ACO in order to account for unique or “special” circumstances. ACOs would bear a tremendous amount of risk under the MSSP, even under the one-sided model, for performance year three. Moreover, the start-up for new organizations and the implementation costs for all ACOs—including contracting, data collection and monitoring—would be quite significant, apart from the additional costs associated with developing and implementing methods and practices to actually achieve improvements in the quality and efficiency of health care delivery.
- ☑ Critical to the financial analysis, of course, is the potential savings an ACO may earn, and there are many financial models that suggest 50 percent of savings (*net* of the 2 percent benchmark percentage for certain one-sided model ACOs) would likely result in relatively modest shared savings payments at best for most, if not all, ACOs. An additional consideration is the timing of such payments, if earned. ACOs would incur most of their costs in the months leading up to the start of the three-year contract term and the first year of the contract. However, the first time in which a shared savings payment would be available would be in the second half of the second year of the three-year term, in order to account for both the

six-month claims run out and calculation of payment amounts (and any amount would be less than 25 percent withheld). Although the ACO participants individually would be paid their FFS amounts during this period, the ACO would be left to bear these major additional costs, including many that are necessitated by compliance with the myriad dictates of the Proposed Regulations.

- ☑ ACOs also must consider the fact that their actual quality and financial performance in performance year one would not be known until mid-year in performance year two, and that changes to address issues and shortcomings would be effective even later in performance year two. Thus, many are wondering whether ACOs can expect to generate any savings before performance year three, if at all. Consequently, it is not surprising that many Medicare providers have been highly critical of the Proposed Regulations and have informed CMS that they do not intend to participate in the MSSP unless significant changes are made to the final rules.⁹⁵

F. Two-Sided Model

Although the ACA specifically requires the Secretary to establish a payment arrangement featuring shared savings, CMS is nevertheless proposing to require ACOs participating in the MSSP to accept both shared savings and shared losses during the initial term of their agreement with CMS. Under the Proposed Regulations, ACOs would have the choice of two separate tracks depending on the extent to which the ACO chooses to accept responsibility for shared losses. As noted previously, under Track One, an ACO would participate only in “upside” shared savings (*i.e.*, one-sided model) in years one and two, but then would transition to responsibility for shared losses and shared savings (*i.e.*, two-sided model) in year three.⁹⁶ In the third year in Track One, CMS would use the same methodology used in year one in Track Two to determine the amount of an ACO’s shared savings and shared losses.⁹⁷ ACOs choosing Track One initially would be required to participate in Track Two for subsequent agreements.⁹⁸ In contrast, an ACO choosing Track Two would be responsible for any losses beginning in year one of the agreement, and would be required to participate in such two-sided risk for any subsequent agreements.⁹⁹ Thus, under both Tracks One and Two, an ACO would be required to participate in the two-sided model at some point in the initial agreement period. This is consistent with the approach advocated by MedPAC prior to the release of the Proposed Regulations, to encourage all ACOs to transition to the two-sided model as soon as possible.¹⁰⁰

1. SUMMARY OF THE TWO-SIDED MODEL

The two-sided model includes many characteristics of the one-sided model. For example, the two-sided model includes an MSR, a shared savings cap, an expenditures benchmark and a sharing rate that is based on the ACO’s performance on quality measures.¹⁰¹ An important distinction, however, is that the two-sided model provides greater incentives for ACOs to achieve shared savings because the percentage of shared savings available to the ACO is greater than in the one-sided model. In addition to the greater potential “upside” rewards of the two-sided model, however, such ACOs would also face an immediate and greater risk for shared losses. The calculation of shared losses is based on a similar formula as the calculation of shared savings in that the amount of shared losses is based on a comparison of actual Medicare FFS claims by attributed beneficiaries to the benchmark expenditures.¹⁰² In addition, there is a minimum loss rate and a shared loss cap designed to limit the total liability of the ACO and help ensure that the shared losses are attributable to actions of the ACO and not what might be considered normal variations.¹⁰³ A more detailed discussion of the characteristics of the two-sided model is set forth below.

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- ☑ ACOs contemplating participation in the MSSP must understand and be comfortable with the two-sided model, since all ACOs will be subject to two-sided risk by no later than their third year of the initial agreement.

2. CMS’S PREFERENCE FOR TWO-SIDED RISK MODEL

CMS believes that risk-based payment models create stronger incentives for an ACO to control costs.¹⁰⁴ To encourage ACO participation in Track Two, CMS is providing the potential for greater financial rewards under the two-sided model. However, CMS acknowledges that the strong incentives to control costs also create the risk that ACOs will “stint on care or undersupply services, shift costs (for instance through changes in referral patterns), as well as increased incentives for providers of services and suppliers to avoid at risk beneficiaries.”¹⁰⁵ CMS has indicated that these risks will require it to more closely scrutinize care patterns and ACO behavior in the two-sided risk model, to ensure that beneficiaries receive appropriate care and that ACOs do not attempt to avoid high-risk beneficiaries.¹⁰⁶ As discussed below, the potential for shared losses also creates

higher capitalization requirements than under the one-sided risk model, necessitating that CMS more closely monitor ACO financial solvency.¹⁰⁷

3. ELEMENTS OF THE TWO-SIDED MODEL

The calculation of shared savings and losses under the two-sided model is meant to create greater incentives for ACOs to participate in Track Two initially; CMS states, “it is both appropriate and essential to provide greater incentives for organizations that participate in the two-sided model.”¹⁰⁸ CMS is proposing that the following features of the one-sided model would operate identically under the two-sided model:

- ACO eligibility criteria
- Beneficiary assignment methodology
- Benchmark and update methodology
- Quality performance standards
- Data reporting requirements
- Data-sharing provisions
- Monitoring for avoidance of at-risk beneficiaries
- Transparency requirements¹⁰⁹

Because of the unique considerations and concerns with regard to the two-sided risk model, certain additional requirements are imposed on ACOs participating in that model. CMS is proposing to create differences in how shared savings are apportioned under the two-sided model. Also, CMS is soliciting comments to determine whether additional requirements are necessary.

a. Beneficiary Notifications and Protections

CMS is not proposing to create any unique beneficiary notification or protection requirements, since it believes that the protections provided in the one-sided model are sufficient to deal with the risk that ACOs will avoid at-risk beneficiaries. Specifically, this risk is minimized by the use of retrospective beneficiary assignment and beneficiary notification requirements that are imposed in the one-sided model. CMS is, however, inviting comments on whether additional protections may be required to ensure that ACOs are not avoiding at-risk beneficiaries.¹¹⁰

b. ACO Eligibility Requirements

Compared to initially one-sided ACOs, ACOs participating in the two-sided model must be capable of repaying CMS for potentially much more significant shared losses. CMS believes the eligibility requirements for ACOs participating in the one-sided model, together with the 25 percent withhold on any shared savings and the required CMS approval of ACO repayment mechanisms, are sufficient to ensure that initially one-sided model ACOs can repay their potential shared losses. However, CMS is seeking comments on whether additional eligibility requirements should be imposed.¹¹¹

c. Quality Performance Measurement and Scoring

The quality performance measurements utilized in the one-sided model will also be utilized in the two-sided model.¹¹² However, the proposed sharing rate would be 60 percent in the two-sided model, as opposed to 50 percent in the one-sided model.¹¹³ This means that each of the five quality measure domains would be worth 12 percent of the potential shared savings. Thus, ACOs delivering higher quality care would continue to receive greater rewards than those delivering lower quality care. For year one, CMS will only require ACOs to fully and accurately report their quality performance data in order to meet the quality performance standard.¹¹⁴ For ACOs participating in Track One, when they transition to the two-sided model in year three of the agreement, the ACO must meet the performance standard that applies in the third year of Track Two, and not merely the full and accurate reporting standard available starting in year one for ACOs choosing Track Two.¹¹⁵

d. *Shared Savings Methodology*

For the two-sided risk model, the shared savings methodology is calculated in a manner similar to the one-sided model, but it provides ACOs with potentially greater monetary rewards for achieving cost savings.

I. MINIMUM SAVINGS RATE

As with the one-sided model, CMS is imposing an MSR under the two-sided model, to ensure that ACO savings are not the result of normal variation in expenses but rather result from the ACO's efforts to achieve greater cost-efficiency.¹¹⁶ Unlike the one-sided model, where the MSR varies based on the number of beneficiaries assigned to the ACO, the MSR under the two-sided model is fixed at 2 percent.¹¹⁷ This is meant both to attract more ACOs to participate in Track 2 in order to take advantage of the fixed MSR and to compensate for the greater risk of losses being assumed by the ACO under the two-sided model.

II. ADDITIONAL SHARED SAVINGS PAYMENTS FOR FQHCS AND RHCS

As noted above, an ACO will be eligible to share in a greater percentage of the savings it generates if it includes FQHCs and/or RHCs as ACO participants. While under the one-sided model where an ACO could be eligible for up to an additional 2.5 percent of shared savings, under the two-sided model an ACO may make up to an additional 5 percent of shared savings available.¹¹⁸ As with the one-sided model, ACOs will receive a larger amount based on the percentage of beneficiaries with one or more visits to an FQHC and/or RHC that is a participant in the ACO during the performance year.¹¹⁹ When added to the sharing rate, this means an ACO in the two-sided model is eligible to receive up to 65 percent of any shared savings.

III. NET SHARING RATE

Under the one-sided model, ACOs are permitted to share in savings net of a 2 percent threshold, meaning that regardless of the MSR applicable to the ACO, it would share in savings beyond 2 percent of the benchmark.¹²⁰ However, under the two-sided risk model, ACO participants are eligible to share first dollar savings as long as the MSR is met.¹²¹ This means that if an ACO generated \$2.1 million in shared savings and met the 2 percent MSR that required savings of \$2 million for the ACO to be eligible for shared savings, the ACO would share in all \$2.1 million in savings. Under the initially one-sided risk model, the same ACO would only share in \$100,000 of savings because of the 2 percent threshold. This disparity is meant to create additional incentives for ACOs to participate in the two-sided risk model.

IV. CALCULATING SHARED LOSSES

Similar features, such as a minimum loss rate, shared loss cap and adjustment of shared losses based on quality performance, are all aspects of the shared loss calculation. The minimum loss rate, like the MSR, is designed to ensure that losses are not the result of more incidental variation but reflect the substantive experience of the ACO.¹²²

In the case of shared losses, quality performance measures serve to reduce, rather than increase, the shared loss rate for the ACO.¹²³ Thus, if an ACO achieves all the quality performance measures and earns the full FQHC and/or RHC adjustment, its shared savings rate would be 65 percent. However, the ACO's shared loss rate will be 35 percent to reflect that quality performance and FQHC and/or RHC adjustments operate to limit an ACO's shared loss rate. As a result, the two-sided model provides ACOs with the chance to earn almost two-thirds of any savings generated while being potentially responsible for only about one-third of shared losses. By minimizing the downside risk and enlarging the upside risk, ACOs are provided with a greater incentive to participate in Track Two.¹²⁴

V. MAXIMUM SHARED SAVINGS AND SHARED LOSS CAP

CMS is also proposing a shared loss cap designed to limit the potential losses an ACO could face under the two-sided model. Under the proposal, the shared loss cap would be phased in by starting at 5 percent of the benchmark in year one, 7.5 percent in year two, and 10 percent in year three.¹²⁵ An ACO beginning in Track One would be subject to the 5 percent benchmark for year three of its initial agreement consistent with the treatment in year one of Track Two. In addition, the shared savings cap under the two-sided model would be 10 percent of the benchmark, 2.5 percent greater than under the one-sided model. Thus, in year one of the two-sided model, an ACO would be eligible to receive up to 10 percent of its benchmark in shared savings while only being at risk for 5 percent of its benchmark in shared losses.

e. *Ensuring ACO Repayment of Shared Losses*

As mentioned previously, risk-based payment models like the two-sided model raise solvency concerns because CMS requires assurances that it will be paid by the ACO for its share of any losses. To protect against the risk of CMS not being paid amounts it is due, CMS proposes to withhold 25 percent of shared savings generated by an ACO over the three-year term.¹²⁶ These withheld amounts would be put towards any shared loss amounts due by the ACO. There is, however, no guarantee that these withheld amounts would be sufficient to cover repayment amounts, and an ACO may be required to repay losses in its first year. In order to address these concerns, CMS proposes to provide ACOs with a range of options for ensuring repayments will be made. An ACO may choose among the following options¹²⁷:

- Obtaining reinsurance
- Placing funds in escrow
- Obtaining surety bonds
- Establishing a line of credit that is evidenced by a letter of credit that the Medicare program can draw upon
- Allowing Medicare to recoup funds from ACO participants. This method, which appears unlikely to be chosen, would require disclosing the percentage of shared losses assigned to each ACO participant, and the ACO would be required to provide signed copies to CMS. ACO participants would also be required to sign agreements with CMS to have their future Medicare payments reduced by the amount reflected in the agreement¹²⁸

Whichever approach is chosen by an ACO, the ACO must ensure that its repayment mechanism is sufficient to cover losses of “at least 1 percent of per capita expenditures for its assigned beneficiaries from the most recent year available.”¹²⁹ The adequacy of the repayment mechanism must be demonstrated prior to an ACO’s participation in the MSSP and then prior to the start of each performance year the ACO participates in the two-sided model.¹³⁰ If an ACO’s losses are not covered by the repayment mechanism, unpaid losses will be carried forward into subsequent years.¹³¹ It should be noted that ACOs choosing either Track One or Two will be required to submit documentation in their initial application demonstrating that they meet the 1 percent standard.¹³² This requires Track One ACOs to obtain sufficient capital to meet the repayment mechanism standard even though they are not exposed to potential losses until year three. CMS believes that “it is important to ensure that prior to entry into the MSSP, the ACO has an appropriate plan for how it will repay any losses incurred during the third year of its agreement when it is automatically transitioned to the two-sided model.”¹³³

f. *Future Participation of Under-Performing Organizations*

Under the Proposed Regulations, ACOs that experience net losses over the three-year initial performance period would not be permitted to reapply to participate in the MSSP. CMS is seeking comments on this proposal, particularly regarding whether it would discourage the participation of smaller ACOs.¹³⁴

g. *Public Reporting*

Under the two-sided model, CMS proposes to require ACOs to publicly report shared losses as well as shared savings.¹³⁵ This is consistent with the requirement that ACOs report shared savings in the one-sided model.

h. *Impact on States*

CMS notes that under the two-sided model (or the third year of the initially one-sided model) there is the potential for state regulation of ACOs as risk-bearing entities. Even though the ACO would not take on the full insurance-type risk for covering the Medicare beneficiaries, there may be state requirements applicable to risk-bearing entities, in addition to the repayment mechanism requirements proposed by CMS, that could apply to ACOs.¹³⁶ CMS is seeking to limit the potential for additional regulation of ACOs under state insurance laws, and is seeking comments on ways to “minimize the burden of any additional regulations.”¹³⁷ Depending on the particular state requirements, the two-sided model creates the potential for stricter state regulation than in the one-sided model, where the ACO does not face the risk of losses until the third contract year. Also, because ACOs participating in the MSSP could potentially assume downside risk in contracts with commercial insurers, the MSSP requirements may not provide sufficient guarantees of solvency for state regulators. Each ACO that is considering

participating in the MSSP should determine which, if any, state requirements could be triggered by the two-sided model (as well as by the third “downside risk” year of the initially one-sided model).

4. VERIFICATION OF SAVINGS AND LOSSES

In order to receive a shared savings payment, the ACO must submit a written request for such payment that certifies the ACO’s compliance with program requirements. The ACO must also certify to the accuracy, completeness and truthfulness of any information submitted by the “ACO, or its participants, or the ACO providers/suppliers, or any other entity to CMS, including any quality data or other information or data relied upon by CMS in determining the ACO’s eligibility for, and the amount of a shared savings payment or the amount owed by the ACO to CMS.”¹³⁸ ACO participants, ACO provider/suppliers and other entities generating or submitting data must also separately certify to the data’s accuracy, completeness and truthfulness.¹³⁹ Presumably, this certification must be directed to CMS, although the Proposed Regulations does not specify.¹⁴⁰

ACTION ITEMS REQUIRED IF YOU WANT TO BECOME AN ACO BY JANUARY 1, 2012

- Evaluate whether the ACO would be better served by participating in Track One or Track Two of the MSSP.
- Determine whether it is feasible to include FQHCs or RHCs as ACO participants in order to gain additional potential shared savings and limit potential shared losses.
- Determine which repayment mechanism to utilize in order to meet the requirements for participating in the MSSP.
- Determine whether there are any state law requirements that would be applicable to an ACO accepting downside risk, and whether those requirements could affect the ACO’s participation in the MSSP.

ACTION ITEMS TO CONSIDER IF YOU WANT TO ASSUME A “READINESS” POSITION WITH RESPECT TO CMS AND BE ABLE TO PROVIDE “ACCOUNTABLE CARE” ON A GOING-FORWARD BASIS

- Acquire, or create a plan of how the ACO will acquire, sufficient capital in order to fund a repayment mechanism meeting CMS requirements.
- Determine any state law requirements that could apply to ACOs and determine what steps may be required to comply with these additional requirements.

MCDERMOTT COMMENTARY: UNANSWERED QUESTIONS AND CHALLENGES PRESENTED BY THE RULE

- Repayment Mechanism Requirements – One particular challenge for ACOs could be that ACOs must demonstrate that they meet the repayment mechanism requirements prior to enrollment. Since providers operating as ACOs may not be subject to minimum reserve requirements prior to participation in the MSSP, ACOs could be forced to generate significant amounts of capital in a short amount of time. This is true not only of ACOs choosing to participate in Track Two, but it also affects those ACOs choosing Track One that must demonstrate that they have a sufficient repayment mechanism in their initial application. This is despite the fact that CMS states that Track One is geared towards ACOs that “may initially lack the . . . capital to accept significant downside risk.”¹⁴¹ Despite this seemingly contrary statement in the preamble, all participating ACOs are required to demonstrate that they have access to sufficient capital to repay CMS in the event of shared losses.
- Each Participating ACO Must Be Willing to Accept Two-Sided Risk – Although Track One provides a transition period for ACOs to gain experience in the MSSP before accepting downside risk, each participating ACO will be forced to accept downside risk at some point in their initial agreement. This could pose a significant barrier to entry for those providers who are either unwilling or lack the capital and relevant expertise to accept downside risk during the initial three-year agreement. As each participating ACO will be required to accept two-sided risk at some point during the initial agreement, state laws regulating risk-bearing entities potentially apply to each participating ACO. Nothing in the Proposed Regulations preempts ACOs from state insurance or risk oversight regulations. In fact, the preamble acknowledges that “some States may regulate risk bearing entities, such as ACOs participating in the two-sided model under the MSSP.”¹⁴² This creates

the potential for additional state licensing or capital requirements applicable to risk-bearing entities, and could increase the burden associated with participating in the MSSP. In states that regulate entities that accept such downside risk, significant additional capital may be required to obtain state licensure or other certification, including required capital reserves and other state regulatory requirements.

- ☑ CMS May Incorporate Additional Payment Models in the Future – In addition to the shared savings payment model that exclusively features shared savings (upside risk) for ACOs, Section 1899(i) of the ACA provides the Secretary with discretion to use capitated and other payment models that the Secretary determines will improve the quality and efficiency of care provided to Medicare beneficiaries.¹⁴³ CMS is not proposing to adopt a partial capitation option at this time, although it will use the Innovation Center to experiment and test various partial capitation payment models, which then may be more widely introduced into the MSSP in the future.¹⁴⁴ The MSSP is likely to evolve and adopt different payment options as CMS gains more experience with alternative payment models and more data concerning the effectiveness of alternative payment models.
- ☑ Financial Losses Could Be Limited by Providing High Quality Care – The two-sided model provides particularly strong incentives to achieve the quality benchmarks necessary to meet the standards in each of the five domains. Because the maximum savings rate is 60 percent, if all the quality performance measures are met, an ACO's shared loss rate could be as low as 40 percent. Thus, in addition to being eligible for additional shared savings, a high-performing ACO can limit its exposure to shared losses. This element may make Track Two a more attractive option for high-performing ACOs.
- ☑ Certification of Data Submitted to CMS – A potential concern also exists with respect to the required certification in connection with the mandatory written request for shared savings. A person in a position to legally bind the ACO (e.g., the CEO or CFO) must certify to the accuracy, completeness and truthfulness of information submitted directly or indirectly to CMS by the ACO and other entities. Given that the ACO's required certification will apply to data generated and submitted by other entities, such as ACO providers/suppliers, the ACO may want entities submitting or generating data on behalf of the ACO to provide the ACO with a separate certification concerning the accuracy, completeness and truthfulness of its data. This certification would be in addition to any certification these entities must provide to CMS concerning the accuracy, completeness and truthfulness of the data.

G. Monitoring and Termination

1. MONITORING

CMS proposes to monitor five areas of ACO operations:

- Avoidance of at-risk beneficiaries
- Compliance with quality performance standards
- Meeting of eligibility requirements
- Notification of beneficiaries of participation in an ACO and ability to opt-out of data sharing
- Marketing materials and activities

CMS plans to conduct monitoring of these areas through a combination of methods, including analysis of data reported by the ACO, site visits, review of complaints and audits.

CMS provides specific steps that will be taken if monitoring identifies deficiencies in compliance with requirements to enroll at-risk beneficiaries and quality performance standards. If CMS identifies that an ACO has trends or patterns that suggest it is avoiding at-risk beneficiaries, the agency may require the ACO to submit a corrective action plan (CAP) as described below. In addition to the corrective actions and termination provisions, CMS proposes additional compliance enforcement steps for ACOs that fail to meet quality reporting requirements. 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. ACOs that failed to report a measure or provided incomplete or inaccurate data would be given an opportunity to

resubmit data and/or provide a written explanation for the reporting deficiencies. ACOs demonstrating a pattern of quality reporting deficiencies could be terminated from the MSSP.

In the preamble, CMS lists six categories of beneficiaries that it would consider “at-risk” for purposes of determining whether an ACO was avoiding at-risk beneficiaries. These categories are as follows:

- High risk score on the CMS-HCC risk adjustment model
- Two or more hospitalizations or emergency room visits each year
- Dually eligible for Medicare and Medicaid
- High utilization pattern
- One or more chronic conditions
- Recent diagnosis that is expected to result in an increased cost

CMS explained that it would use a combination of claims analysis and other beneficiary-level documentation to determine avoidance of these beneficiaries, but did not provide details on how this information would be evaluated. In some circumstances, the nature of the care required by beneficiaries defined by CMS as “at-risk” may result in the beneficiary voluntarily choosing to seek care outside of an ACO. Beneficiaries with chronic conditions or recent diagnoses may seek care from specialists or experts in their condition that are not associated with the ACO. Furthermore, such beneficiaries may perceive assignment to an ACO as an attempt to ration their care and may choose to seek services elsewhere. As a result, data regarding patient assignment to the ACO could appear to show that the ACO was avoiding such beneficiaries, when, in reality, the beneficiaries voluntarily opted to receive care outside of the ACO.

CMS requests comments on the proposed definition of “at-risk beneficiary” and additional beneficiary characteristics that should be considered. CMS also seeks comments regarding potential penalties for ACOs found to have avoided at-risk beneficiaries. The current Proposed Regulations would require a CAP, followed by program termination for failure to demonstrate improvement in response to the CAP. Other possible penalties mentioned by CMS include cessation of, or reduction in, the assignment of new beneficiaries to the ACO, reduction in the amount of the shared savings payment, or a fine for each instance of at-risk beneficiary avoidance.

ACTION ITEM

- Potential ACOs should review the five operational areas that are enumerated for monitoring purposes and make sure that policies and procedures are put in place to ensure compliance in these areas. It will be important to ensure that the selection of ACO participants and ACO providers/suppliers will not result in assignment of beneficiaries to the ACO in a manner that could be interpreted as intentional avoidance of at-risk beneficiaries. Similarly, the ACO should evaluate the existing quality performance of potential ACO participants and ACO providers/suppliers, to determine if there is a risk of failure to meet quality performance standards during the performance period.

2. CORRECTIVE ACTION PLANS

The Proposed Regulations provide steps that CMS may take prior to termination of an agreement for failure to meet program requirements. CMS could first provide the ACO with a warning notice, request a CAP from the ACO or place the ACO on a special monitoring plan.

The Proposed Regulations do not provide details regarding the process for issuing warning notices or placing the ACO on a special monitoring plan, but do provide further information for the CAP process. Failure to comply with CAP procedures or demonstrate improved performance following completion of the CAP could result in termination from the MSSP.

Under the Proposed Regulations, an ACO would be ineligible to receive shared savings while under a CAP or earn any shared savings for any period attributable to time while the ACO was under a CAP. Depending on the timing of the shared savings payments and the length of time that a CAP is in effect, this could result in an ACO not receiving shared savings

payments for periods during which it was in full compliance with MSSP requirements and potentially forfeiting shared savings payments for the entire three-year agreement period. CMS does not propose to provide partial payments based on the severity of action leading to the CAP or otherwise permit payments for periods that the ACO met program requirements. In addition, CMS does not discuss the ACO's liability for shared losses incurred while under a CAP or for periods attributable to the time under the CAP. As drafted, it appears that the ACO would be liable for shared losses during these periods.

ACTION ITEM

- Potential ACOs should review the list of actions that could result in an ACO becoming subject to a CAP (*i.e.*, those actions that could result in termination of an ACO agreement, plus incurring large losses to the Medicare program) and institute policies and procedures to reduce the potential that a CAP would be necessary.

3. TERMINATION

CMS proposes to be able to terminate an ACO for 16 reasons, including, but not limited to the following:

- Avoidance of at-risk beneficiaries
- Failure to meet quality performance standards
- Failure to comply with beneficiary notice requirements regarding ACO provider/supplier participation in the ACO
- Use of unapproved marketing materials or activities
- Failure to maintain an assigned beneficiary population of at least 5,000
- Failure to offer beneficiaries the option to opt out of sharing claims information
- Limiting access to beneficiary summary reports or other records
- Failure to demonstrate adequate resources to repay losses and maintaining those resources for the agreement period

ACOs would also have the option to voluntarily terminate participation in the MSSP. The ACO would be required to provide at least 60 days' notice of termination to CMS and notify beneficiaries of the ACO's decision to terminate using materials that meet ACO marketing material guidelines. ACOs that are terminated from the MSSP would have the option to re-apply after the end of the three-year agreement period. Termination of an agreement for any reason would result in forfeiture by the ACO of the 25 percent withhold of shared savings.

CMS specifically requests comments on other conditions that should merit termination of an ACO agreement.

ACTION ITEM

- ACOs should review the list of actions that could result in termination of an agreement and institute policies and procedures to reduce the potential for termination.

McDERMOTT COMMENTARY

- CMS proposes that if an agreement is terminated, whether voluntarily or involuntarily, any withhold payments associated with that agreement would be forfeited. Because the withhold amounts are based on 25 percent of FFS-based shared savings payments made to the ACO during the performance period, the withhold amount retained by CMS would necessarily include both potential under- and overpayment amounts. It is not clear how reconciliation of under- and overpayments would account for the retained withhold amounts.

4. RECONSIDERATION REVIEW PROCESS

As required by statute, CMS is proposing that no reconsideration, appeal, administrative or judicial review be permitted for the following determinations:

- Specifications of quality and performance standards
- Assessment of quality of care furnished by an ACO under the performance standards
- Assignment of beneficiaries to the ACO
- Determination of eligibility for shared savings, the amount of shared savings, the estimated per capita Medicare expenditures under the ACO for beneficiaries assigned to the ACO and the average benchmark for the ACO
- Percentage of shared savings specified by the Secretary and the total amount of shared savings
- Termination for failure to meet quality performance standards
- Determination made by the reviewing antitrust agency that it is likely to challenge or recommend challenging the ACO

For all other determinations, an ACO would be able to request a redetermination by written request to an authorized official. The burden of proof would be on the ACO to demonstrate that the initial determination was not consistent with CMS regulations or statutory authority. If any of the parties disagree with the recommendation of the reconsideration official, they may request record review of the initial determination and recommendation by an independent CMS official. The decision of the independent CMS official would be final.

McDERMOTT COMMENTARY

- CMS seeks comments on the appropriate review process for terminations based on avoidance of at-risk beneficiaries. It is not clear why CMS specifically seeks comments related to this one basis for program termination or if CMS is proposing to create a separate reconsideration review process for just terminations resulting from avoidance of at-risk beneficiaries.

5. AUDITS AND RECORD RETENTION

CMS proposes to require that the ACO and its ACO participants, ACO providers/suppliers and other contracted entities agree to have all relevant materials that relate to the ACO's compliance with program requirements, quality of services, determination of amount due to or from CMS, and ability to bear risk or repay losses be available for audit, inspection and evaluation by the U.S. Department of Health and Human Services (DHHS), the Comptroller General or Office of the Inspector General (OIG). Accordingly, CMS would require that the ACO, ACO participants, ACO providers/suppliers and contracted entities maintain materials that relate to the above issues for the later of 10 years from the final date of the agreement period or date of completion of any audit, inspection or evaluation. CMS also proposes that, with at least 30 days notice prior to the end of the otherwise applicable retention period, CMS could require retention for longer periods of time in certain circumstances, including termination of the agreement or allegations of fraud.

ACTION ITEM

- Potential ACOs must ensure that their agreements with other entities and individuals include the appropriate record retention and audit accessibility provisions.

H. Coordination with Other Agencies

In developing the MSSP, CMS worked closely with other agencies, including the DHHS OIG, the IRS and the Federal Trade Commission (FTC), to facilitate participation and to ensure a coordinated and aligned effort in the implementation of the MSSP. As discussed in further detail below, the results of CMS's collaboration with these agencies and the exact model that a proposed ACO must follow to fall within the applicable exceptions created by these agencies remain to be seen.

1. WAIVERS OF CMP, ANTI-KICKBACK AND PHYSICIAN SELF-REFERRAL LAWS

ACA grants the Secretary authority to waive certain fraud and abuse laws as necessary to carry out the provisions of the MSSP. Concurrent with the release of the MSSP's Proposed Regulations, CMS and the Inspector General for DHHS released a notice with comment period (the Waivers Notice), which then was published in the *Federal Register* on April 7, 2010.¹⁴⁵ The Waivers Notice proposes waivers of the Stark law, federal anti-kickback statutes and the civil monetary penalty law as they apply to certain financial arrangements between and among ACOs and their constituent providers and suppliers. CMS anticipates that the waivers applicable to ACOs will be issued concurrently with its publication of the MSSP final rule.

McDERMOTT COMMENTARY

- ☑ For more detail on the proposed waivers, see McDermott *White Paper* "The Proposed Waivers of the Fraud & Abuse Laws for ACOs: Have OIG and CMS Gone Far Enough?" available at <http://www.mwe.com/info/news/wp0511b.pdf>.

2. IRS GUIDANCE RELATING TO TAX-EXEMPT ORGANIZATIONS

The IRS intends to solicit public comment on whether existing guidance related to the Internal Revenue Code provisions governing tax-exempt organizations is sufficient for those tax-exempt organizations planning to participate in the MSSP through ACOs, and, if not, what additional guidance is needed. CMS explained that it will continue to work with the IRS to ensure a coordinated effort in the implementation of the MSSP.

McDERMOTT COMMENTARY

- ☑ For more detail, see McDermott *On the Subject* "Tax-Exempt Hospitals and Accountable Care Organizations," available at <http://www.mwe.com/info/news/ots0411l.htm>.

3. ANTITRUST POLICY STATEMENT

The FTC and U.S. Department of Justice (collectively, the Antitrust Agencies), which jointly enforce federal antitrust laws, issued a proposed Statement of Antitrust Enforcement Policy Regarding ACOs Participating in the MSSP (the Antitrust Policy Statement).¹⁴⁶ The Antitrust Policy Statement applies to collaborations among providers and provider groups formed after March 23, 2010, that have otherwise been approved to participate as ACOs in the MSSP, and sets forth an antitrust "Safety Zone" for certain ACOs. Under the Safety Zone concept, the Antitrust Agencies will not challenge an ACO that otherwise meets CMS's criteria to participate in the MSSP (a) if ACO participants that provide the same service have a combined share of 30 percent or less of each common service in each ACO participant's Primary Service Area (PSA), or (b) if ACO participants that meet the "Rural Exception" under the Antitrust Policy Statement have 50 percent or less of combined PSA share for a common service. CMS proposes that an ACO that falls within the Safety Zone would not be required to obtain Antitrust Agency review as a condition of participation.

McDERMOTT COMMENTARY

- ☑ For more detail, see, McDermott *White Paper* "FTC/DOJ Issue Joint Proposed Statement of Antitrust Enforcement Policy Relating to ACOs," available at <http://www.mwe.com/info/pubs/wp0411a.pdf>.

4. PROHIBITION AGAINST THE SHARED SAVINGS PROGRAM PARTICIPATION BY ACOS WITH MARKET POWER

a. *Coordinating the Shared Savings Program Application with the Antitrust Agencies*

CMS proposes to require that, except for an ACO that qualifies for the Rural Exception, an ACO with a PSA share above 50 percent for any common service that two or more ACO participants provide to patients for the same PSA must submit, as part of its Program application, a letter from the Antitrust Agency confirming that it has no intent to challenge the proposed ACO. Without such a letter, the ACO's application would be denied.

If a proposed ACO is outside the Safety Zone, but below the 50 percent mandatory review threshold, CMS takes the position that it may still be pro-competitive. The Antitrust Policy Statement highlights how ACOs in this category may proceed without Agency scrutiny, including by identifying five types of conduct that an ACO can avoid to reduce the likelihood of antitrust investigation. An ACO within this category may also seek an expedited review from the Antitrust Agencies.

The Proposed Regulations also discuss the proposed procedure for handling a material change in the participant and/or supplier composition of an ACO. If any revised PSA share is calculated to be greater than 50 percent, the ACO will be subject to mandatory review or re-review by the Antitrust Agencies in order to maintain eligibility in the MSSP. CMS proposes that, if the ACO fails to obtain a letter from the reviewing Antitrust Agency confirming that it has no intent to challenge the ACO, the ACO will be terminated from the MSSP.

b. *Competition and Quality of Care*

The CMS Proposed Regulations explain that even though ACOs participating in the MSSP will not compete on the basis of price, they will compete to serve Medicare beneficiaries on the basis of other dimensions, such as quality of care, innovations that improve care and choice in treatment options. The Proposed Regulations cite studies that demonstrate that the presence of regulated prices fosters improved quality, and explain that competition among ACOs may motivate innovation, accelerate the development of evidence-based practices, raise the likelihood of preserving alternatives in the market and provide better benchmarks for quality improvements.

c. *Competition, Price and Access to Care*

The Proposed Regulations acknowledge that a concern with potential ACO market power in the commercial and Medicare markets is warranted because health care providers are more likely to create ACOs under the MSSP if they can use the same ACOs to serve both Medicare beneficiaries and patients covered by commercial insurance. The concern is that newly created ACOs with market power could raise prices to private payers, since prices are not regulated in the commercial market. Higher commercial prices create disparities in payment rates between commercial payers compared to Medicare rates, and higher levels of profitability. The concern is that ACOs may wish to increase private pay patients and reduce the number of Medicare patients, thus limiting access to care for Medicare beneficiaries. For this reason, CMS proposes that coordination with the Antitrust Agencies is essential, and it plans to continue to work with the Antitrust Agencies to determine the extent to which additional actions may be appropriate with regard to ACOs participating in the MSSP.

McDERMOTT COMMENTARY

- ☑ At this time, the design and application of waivers for certain fraud and abuse laws; IRS guidance with regard to tax-exempt organizations forming ACOs; the application of antitrust policy by the Antitrust Agencies; and the methods for coordination between CMS, the OIG, the IRS and the Antitrust Agencies still remain to be seen. The ability of these agencies to agree upon coordinated and integrated policies and processes will be integral to the success of the MSSP.

I. Overlap with Other CMS Shared Savings Initiatives

Statutory language prohibits participation in multiple CMS initiatives that involve shared savings. Consequently, CMS proposes to prohibit Medicare providers and suppliers from participation in the MSSP as ACO participants if the providers/suppliers are participating in (a) the Independence at Home Medical Practice Demonstration Program, (b) the Medicare Health Care Quality Demonstration Program, (c) medical home demonstrations with a shared savings element, (d) the Physician Group Practice Transition Demonstration or (e) any other Medicare initiative that involves shared savings. Participants in the Physician Group Practice Demonstration that apply to participate in the MSSP would be required to complete a condensed application form.

In the preamble to the Proposed Regulations, CMS provides significantly more detail regarding its proposed implementation of the restriction of participation in multiple shared savings programs. ACO participants would be prohibited from participating in multiple shared savings programs. However, individual ACO providers/suppliers would not be similarly prohibited. Such providers/suppliers could participate in the MSSP and another shared savings program so long as the provider/supplier submits claims under separate TINs for each shared savings program.

Finally, although the Proposed Regulations do not provide details regarding the future demonstration programs to be conducted by the Center for Medicare and Medicaid Innovations (CMMI), in the preamble text CMS requests comments regarding the best methods for the CMMI to test different payment models that would provide financial and technical assistance to groups that may wish to form ACOs.

McDERMOTT COMMENTARY

- ☑ For more details on the Pioneer ACO Model, see McDermott *On the Subject* "The 'Pioneer' Model: CMS's Alternative Shared Savings Program for ACOs," available at <http://www.mwe.com/info/news/ots0511h.htm>.
- ☑ Potential ACOs must evaluate the proposed ACO regulations and available information regarding potential demonstration programs involving shared savings that might emerge from the CMMI. Although CMS has not provided any information on the specific shared savings demonstration programs that the CMMI might conduct, it appears relatively certain that the CMMI will conduct some demonstration programs that involve shared savings. Whether these programs may include elements similar to those in the proposed ACO regulations remains to be determined, although implementation of such models is likely. Therefore, because an organization cannot participate in more than one shared savings program, potential ACOs must weigh the risks of entering into an agreement with CMS under the proposed MSSP rules or waiting to see what types of shared savings demonstrations will come out of the CMMI.

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EXHIBIT A

- **Domain 1: Patient/Caregiver Experience**

- Clinician/Group CAHPS¹⁴⁷: Getting Timely Care, Appointments and Information
- Clinician/Group CAHPS: How Well Your Doctors Communicate
- Clinician/Group CAHPS: Helpful, Courteous, Respectful Office Staff
- Clinician/Group CAHPS: Patients' Rating of Doctor
- Clinician/Group CAHPS: Health Promotion and Education
- Clinician/Group CAHPS: Shared Decision-Making
- Medicare Advantage CAHPS: Health Status/Functional Status
- TOTAL: 7 measures

- **Domain 2: Care Coordination**

- **Transitions**
 - Risk-Standardized, All Condition Readmission
 - 30 Day Post-Discharge Physician Visit
 - Medication Reconciliation
 - Care Transition Measure
 - Ambulatory Sensitive Conditions Admissions: Diabetes, Short-Term Complications
 - Ambulatory Sensitive Conditions Admissions: Uncontrolled Diabetes
 - Ambulatory Sensitive Conditions Admissions: Chronic Obstructive Pulmonary Disease
 - Ambulatory Sensitive Conditions Admissions: Congestive Heart Failure
 - Ambulatory Sensitive Conditions Admissions: Dehydration
 - Ambulatory Sensitive Conditions Admissions: Bacterial Pneumonia
 - Ambulatory Sensitive Conditions Admissions: Urinary Infections
- **Information Systems**
 - Percentage of All Physicians Meeting Stage 1 HITECH Meaningful Use Requirements
 - Percentage of PCPs Meeting Stage 1 HITECH Meaningful Use Requirements
 - Percentage of PCPs Using Clinical Decision Support
 - Percentage of PCPs Who Are Successful Electronic Prescribers Under the eRx Incentive Program
 - Patient Registry Use
- TOTAL: 16 measures

- **Domain 3: Patient Safety**

- Hospital-Acquired Conditions Composite (including Foreign Object Retained After Surgery, Air Embolism, Blood Incompatibility, etc.)
- Hospital-Acquired Conditions: CLABSI¹⁴⁸ Bundle
- TOTAL: 2 measures

- **Domain 4: Preventive Health**

- Influenza Immunization
- Pneumococcal Vaccination
- Mammography Screening
- Colorectal Cancer Screening
- Cholesterol Management for Patients with Cardiovascular Conditions
- Adult Weight Screening and Follow-Up
- Blood Pressure Measurement
- Tobacco Use Assessment and Tobacco Cessation Intervention
- Depression Screening
- TOTAL: 9 measures

- **Domain 5: At-Risk Population/Frail Elderly Health**

- **Diabetes**

- Diabetes Composite (All or Nothing Scoring)
- Diabetes Mellitus: Hemoglobin A1c Control (< 8 percent)
- Diabetes Mellitus: Low Density Lipoprotein (LDL-C) Control
- Diabetes Mellitus: Tobacco Non-Use
- Diabetes Mellitus: Aspirin Use
- Diabetes Mellitus: Hemoglobin A1c Poor Control (< 9 percent)
- Diabetes Mellitus: High Blood Pressure Control
- Diabetes Mellitus: Urine Screening for Microalbumin or Medical Attention for Nephropathy in Diabetic Patients
- Diabetes Mellitus: Dilated Eye Exam in Diabetic Patients
- Diabetes Mellitus: Foot Exam

- **Heart Failure**

- Heart Failure: Left Ventricular Function (LVF) Assessment
- Heart Failure: LVF Testing
- Heart Failure: Weight Measurement
- Heart Failure: Patient Education
- Heart Failure: Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD)
- Heart Failure: Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for LVSD
- Heart Failure: Warfarin Therapy for Patients with Atrial Fibrillation

- **Coronary Artery Disease**

- Coronary Artery Disease (CAD) Composite: All or Nothing Scoring
- CAD: Oral Antiplatelet Therapy Prescribed for Patients with CAD
- CAD: Drug Therapy for Lowering LDL Cholesterol
- CAD: Beta-Blocker Therapy for CAD Patients with Prior Myocardial Infarction
- CAD: LDL Level < 100 mg/dl
- CAD: ACE or ARB Therapy for Patients with CAD and Diabetes and/or LVSD

- **Hypertension**

- Hypertension: Blood Pressure Control
- Hypertension: Plan of Care

- **Chronic Obstructive Pulmonary Disorder**

- Chronic Obstructive Pulmonary Disorder: Spirometry Evaluation
- Chronic Obstructive Pulmonary Disorder: Smoking Cessation Counseling Received
- Chronic Obstructive Pulmonary Disorder: Bronchodilator Therapy Based on FEV1

- **Frail Elderly**

- Falls: Screening for Fall Risk
- Osteoporosis Management in Women Who Had a Fracture
- Monthly INR for Beneficiaries on Warfarin
- TOTAL: 31 measures

EXHIBIT B

- **Domain 1: Proposed for Medicare Shared Savings Program – Accountable Care Organizations**
 - Patient/Caregiver Experience
 - Care Coordination
 - Patient Safety
 - Preventive Health
 - At-Risk Population/Frail Elderly Health

- **Domain 2: Proposed for Initial Core Set of Health Quality Measures for Medicaid-Eligible Adults**
 - Prevention and Health Promotion
 - Management of Acute Conditions
 - Management of Chronic Conditions
 - Family Experiences of Care
 - Availability

- **Domain 3: Proposed for Hospital Inpatient Value-Based Purchasing Program**
 - Process Measures
 - Outcome Measures
 - Survey Measures

- **Domain 4: National Health Care Quality Strategy and Plan**
 - Patient-Centeredness and Family Engagement
 - Eliminating Disparities in Care
 - Better Care
 - Affordable Care
 - Healthy Communities

¹ Klar, Ron, “The Importance of the Shared-Savings ACO Model,” Health Affairs, Jan. 25, 2011, available at: <http://healthaffairs.org/blog/2011/01/25/the-importance-of-the-shared-savings-aco-model/>. Klar goes on to state, “There will be no financial penalties or down-side risks for these groups other than their unreimbursed services and other investments. The SSM is not yet another version of managed care by at-risk entities for enrolled beneficiaries.”

² <http://edocket.access.gpo.gov/2011/pdf/2011-7880.pdf>.

³ CMS is accepting comments on the Proposed Regulations through June 6, 2011.

⁴ See Centers for Medicare and Medicaid Services, Office of Public Affairs, *Summary of the Proposed Regulations Provisions for Accountable Care Organizations Under The Medicare Shared Savings Program*, available at: http://www.cms.gov/MLNProducts/downloads/ACO_NPRM_Summary_Factsheet_ICN906224.pdf.

⁵ 10.1056/nejmp1100950 nejm.org.

⁶ <http://www.aha.org/aha/content/2011/pdf/aco-white-paper-cost-dev-aco.pdf>.

⁷ 42 CFR 425.5(d)(1). Note: All references to CFR citations are as currently proposed under the Proposed Regulations.

⁸ Id.

⁹ 42 CFR 425.5(d)(3); 42 CFR 425.18(b).

¹⁰ Id.

¹¹ Id.

¹² Id.

¹³ 42 CFR 425.14(d)(1).

¹⁴ 42 CFR 425.14(c).

¹⁵ 42 CFR 425.5(d)(11).

¹⁶ 42 CFR 425.5(d)(15).

¹⁷ 42 CFR 425.5(d)(15)(ii)(A).

¹⁸ One alternative CMS identifies is allowing both a January 1 and a July 1 start date in the first MSSP year. ACO agreements with a July 1 start date would have a 3.5-year term and an 18-month performance measurement period as the first measurement period under the agreement.

¹⁹ A “claims-run-out period” is the time between when a Medicare-covered service has been furnished to a beneficiary and when the final payment is actually issued for the respective service. According to CMS, “. . . the longer the claim run-out period, the more complete and accurate the utilization and expenditure data would be for any given year . . . [and h]igher completion percentages are associated with longer run out periods and thus would necessitate a longer delay before [CMS] could determine whether an ACO is eligible to receive shared savings and provide performance feedback.”

²⁰ The corresponding quality measures in the Proposed Regulations are intended to align with existing (and likely future) Medicare incentive programs measures, such as those used in the Physician Quality Reporting System (PQRS), Electronic Prescribing Incentive Program, Electronic Health Record (EHR) meaningful use incentive programs, Hospital Inpatient Quality Reporting Program, and Medicaid and public-sector reporting initiatives. As such, the measures overlap significantly with existing measures collected for other health care program reporting purposes and are geared toward achieving consistency across ACOs and providing opportunities for care improvement.

²¹ The proposal to share this data is based in part on favorable feedback received in the PGP Demonstration, the RFI comments on the MSSP, and MSSP Open Door Forums. The Proposed Regulations state that the aggregated data provided by CMS will omit the 18 identifiers listed in the HIPAA Privacy Rule (45 CFR 164.514(b)).

²² CMS notes in particular that having such data would enable an ACO to identify and avoid at-risk beneficiaries so as to exclude the costs of those beneficiaries in the calculation of actual expenditures during a performance year.

²³ For example, historical, beneficiary-identifiable data would enable CMS to evaluate an ACO on the quality and cost of care provided to beneficiaries who chose to receive care from the ACO and encourage the ACO to redesign its care processes for all beneficiaries, not just for the subset upon whom the ACO is being evaluated.

²⁴ According to the Proposed Regulations, the minimum necessary data for Medicare Parts A and B may include beneficiary ID, date, date of birth, gender, date of death (if applicable), claim ID, the from and through dates of service, the provider or supplier ID, and the claim payment type. The minimum necessary data for Part D may include beneficiary ID, prescriber ID, drug service date, drug product service ID, quantity dispersed, days supplied, gross drug cost, brand name, generic name, drug strength and an indication of whether the drug is on the formulary as designated by CMS.

²⁵ Again, the provisions of state laws that impose additional restrictions on certain categories of sensitive information (*e.g.*, HIV/AIDS, mental health, genetic testing, genetic counseling, sexually-transmitted diseases) do not apply to the sharing of data by CMS and thus are not directly implicated by the data sharing provisions.

²⁶ See Section II.D of the Proposed Regulations for the communication plan requirements generally. CMS considered the relative merits of using an opt-in rather than an opt-out, taking into account the relative merits identified by various health information exchange initiatives across the United States, and rejected the opt-in approach primarily because of the affect it would have on beneficiary participation and the additional administrative burdens it would impose on physician practices. To be meaningful, an opportunity to opt out must (a) provide advance notice and time to make the opt-out decision, (b) provide adequate information about how the information will be shared and used and the benefits and risks of making their data available for the proposed uses, (c) not compel consent, and (d) not use the choice to permit the information to be used for discriminatory purposes.

²⁷ The description of the DUA under the Proposed Regulations lacks some of the components required for a data use agreement under the HIPAA Privacy Rule. See 45 CFR 164.514(e)(4).

²⁸ See 42 U.S.C. § 290dd-2 and implementing regulations at 42 CFR Part 2. Note, a consent required under this law differs from the opt-out requirement of the Proposed Regulations.

²⁹ CMS's insights and observations concerning the importance of the timeliness of the data emanate largely from feedback received in the PGP Demonstration, the RFI comments on the MSSP, and MSSP Open Door Forums.

³⁰ The Proposed Regulations state that the aggregated data provided by CMS will omit the 18 identifiers listed in the HIPAA Privacy Rule (45 CFR 164.514(b)).

³¹ Financial performance information included number of patients seen, number of patients assigned, per capita expenditures, risk score, benchmark, total assigned beneficiary expenditures, minimum savings account, shareable savings and annual performance payment.

³² Quality performance information included numerator, denominator and rate for each measure along with the target benchmark for each measure.

³³ Aggregated beneficiary population metrics included a breakdown of the population into high-risk score beneficiaries; beneficiaries with one or more hospitalizations; and chronic disease subpopulations, such as patients with congestive heart failure, coronary artery disease, hypertension, chronic obstructive pulmonary disease and diabetes.

³⁴ Aggregated encounter data included the number of patients overall and in each subpopulation with emergency department visits, hospital discharges, physician visits and their corresponding rate for the assigned population.

³⁵ The Health Insurance Portability and Accountability Act of 1996 and implementing regulations at 42 CFR § 160, *et seq.*

³⁶ 42 U.S.C. § 290dd-2 and implementing regulations at 42 CFR Part 2.

³⁷ 5 U.S.C. § 552a(b). As noted above, the Proposed Regulations' data sharing provisions focus only on the sharing of data by CMS with ACOs, not on internal data sharing between and among an ACO's participants and providers/suppliers for treatment, health care operations or other purposes. Therefore, the Proposed Regulations do not identify or analyze federal or state law restrictions that would limit such internal data sharing within the ACO.

³⁸ 73 Fed. Reg 30664.

³⁹ 45 CFR § 164.501. The first and second paragraphs include the following activities: (a) conducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines, provided that the obtaining of generalizable knowledge is not the primary purpose of any studies resulting from such activities; population-based activities relating to improving health or reducing health care costs, protocol development, case management and care coordination, contacting of health care providers and patients with information about treatment alternatives; and related functions that do not include treatment; and (b) reviewing the competence or qualifications of health care professionals, evaluating practitioner and provider performance, health plan performance, conducting training programs in which students, trainees or practitioners in areas of health care learn under supervision to practice or improve their skills as health care providers, training of non-health care professionals, accreditation, certification, licensing or credentialing activities.

⁴⁰ See 45 CFR § 164.506(c)(4).

⁴¹ The Proposed Regulations do not address internal data sharing of the CMS identifiable beneficiary data within the ACO itself. Therefore, it was unnecessary to consider the basis under HIPAA for the ACO participants and providers/suppliers to share with one another the claims data received from CMS for beneficiaries with whom some or all of them may not have had a provider/supplier relationship. An ACO will need to consider that HIPAA compliance dimension in connection with its internal data sharing strategy and in that context may need to rely on other HIPAA compliance theories. For that same reason, an ACO will also need to analyze and develop strategies for complying with state statutes and regulations that impose restrictions on the use and disclosure of special categories of identifiable information (*e.g.*, mental health, HIV/AIDS, genetic testing, genetic counseling, sexually transmitted diseases) that are in addition to or more stringent than those imposed by HIPAA but are not applicable to CMS's use and disclosure of such information.

⁴² Query whether the provision of beneficiary-identifiable claims data by CMS to the ACO, and subsequent use of the data by the ACO, would also qualify as a disclosure and subsequent use for payment purposes under HIPAA.

⁴³ See 42 U.S.C. § 290dd-2 and implementing regulations at 42 CFR Part 2.

⁴⁴ 42 CFR 423.505(f)(30(v), (vi)).

⁴⁵ 73 Fed. Reg. 30666.

⁴⁶ From § 425.10(b)(i) and (ii) of the Proposed Regulations.

⁴⁷ The one-sided and two-sided risk models are discussed in this paper.

⁴⁸ From § 425.10(b) of the Proposed Regulations.

⁴⁹ *Id.*

⁵⁰ Medicare fee-for-service rates will be determined by getting a data sample and modeling the measures. For the Medicare Advantage rates, CMS will check the distribution from annual Medicare Advantage quality performance data and set the benchmark accordingly. Since Medicare Quality performance rates use both claims and clinical data, CMS proposes to use those rates when they are available.

⁵¹ For more detail, see 76 Fed. Reg. 19571-19591.

⁵² For more detail, see 76 Fed. Reg. 19595.

⁵³ For more detail, see 76 Fed. Reg. 19571-19591.

⁵⁴ 9 measures x 2 points maximum/measure.

⁵⁵ $(16.2/18) \times 100 = 90$ percent.

⁵⁶ 90 percent x 50 percent = 45 percent.

⁵⁷ 90 percent x 60 percent = 54 percent.

⁵⁸ Eligible professionals include physicians, practitioners as described in § 1842(b)(18)(C) of ACA, physical and occupational therapists, qualified speech-language pathologists and qualified audiologists (§ 1848(k)(3)(B)).

⁵⁹ For more detail, see 76 Fed. Reg. 19599.

⁶⁰ As defined in the HITECH Act.

⁶¹ For instance, ACA makes aggregate information on physician resource use and quality data for long-term care hospitals, inpatient rehabilitation facilities, hospices and some cancer hospitals publicly available (§§ 3003 – 3005).

⁶² For more detail, see 76 Fed. Reg. 19601.

⁶³ SSA § 1899(d)(1) (42 U.S.C. § 1395jjj(d)(1)).

⁶⁴ 76 Fed. Reg. at 19604.

⁶⁵ 76 Fed. Reg. at 19603-4.

⁶⁶ 42 C.F.R. § 425.7(b); 76 Fed. Reg. at 19604-6.

⁶⁷ 42 C.F.R. § 425.7(b)(1); 76 Fed. Reg. at 19604-6.

⁶⁸ SSA § 1899(d)(1)(B)(ii) (42 U.S.C. § 1395jjj(d)(1)(B)(ii)).

⁶⁹ 76 Fed. Reg. 19608-9.

⁷⁰ 76 Fed. Reg. 19608.

⁷¹ 76 Fed. Reg. at 19609.

⁷² 42 C.F.R. § 425.7(b)(7).

⁷³ 76 Fed. Reg. at 19609.

⁷⁴ 76 Fed. Reg. at 19610.

⁷⁵ 42 C.F.R. § 425.7(b)(2); 76 Fed. Reg. at 19609-10.

⁷⁶ 76 Fed. Reg. at 19606.

⁷⁷ 76 Fed. Reg. at 19607.

⁷⁸ 76 Fed. Reg. at 19607.

⁷⁹ 76 Fed. Reg. at 19608-9.

⁸⁰ 42 C.F.R. § 425.7(b)(3).

⁸¹ 42 C.F.R. § 425.7(b)(4).

⁸² 76 Fed. Reg. at 19605.

⁸³ 42 C.F.R. § 425.7(b)(5); 76 Fed. Reg. at 19605.

⁸⁴ 42 C.F.R. § 425(b)(6).

⁸⁵ The Proposed Regulations also address how, under Option Two, per capita expenses would be determined for beneficiaries without three full years of immediately prior Medicare claims data. 76 Fed. Reg. at 19605-6.

⁸⁶ SSA § 1899(d)(i)(B)(i) (42 U.S.C. § 1395jjj(d)(1)(B)(i)).

⁸⁷ 42 C.F.R. § 425.7(c)(2); 76 Fed. Reg. at 19611-2. CMS's table setting out its anticipated CI application and corresponding MSR can be found at proposed 42 C.F.R. § 425.7(c)(2) and 76 Fed. Reg. at 19646.

⁸⁸ 42 C.F.R. § 425.7(c)(4).

⁸⁹ 42 C.F.R. § 425.7(c)(4); 76 Fed. Reg. at 19613.

⁹⁰ 76 Fed. Reg. at 19613.

⁹¹ 42 C.F.R. §§ 425.7(c)(7), 425.10.

⁹² SSA § 1899(d)(2) (42 U.S.C. § 1395jjj(d)(2)).

⁹³ 76 Fed. Reg. at 19615.

⁹⁴ 42 C.F.R. § 425.5(d)(b)(iii).

⁹⁵ Letter from Donald W. Fischer, President and CEO, American Medical Group Association, to Dr. Donald M. Berwick, Administrator, Centers for Medicare and Medicaid Services (May 11, 2011).

⁹⁶ *Id.* at § 425.5(d)(6)(i)(A).

⁹⁷ *Id.*

⁹⁸ *Id.* at § 425.5(d)(6)(ii).

⁹⁹ *Id.* at § 425.5(d)(6).

¹⁰⁰ Letter from Glenn M. Hackbarth, Chairman, Medicare Payment Advisory Commission, to Dr. Donald M. Berwick, Administrator, Centers for Medicare and Medicaid Services (Nov. 22, 2010).

¹⁰¹ *Id.* at § 425.7(d).

¹⁰² *Id.* at § 425.7(d)(1).

¹⁰³ *Id.* at §§ 425.7(d)(2), (d)(9).

¹⁰⁴ *Id.*

¹⁰⁵ *Id.*

¹⁰⁶ *Id.*

¹⁰⁷ *See id.* at 19622.

¹⁰⁸ 76 Fed. Reg. at 19618.

¹⁰⁹ *Id.*

¹¹⁰ *Id.* at 19619.

¹¹¹ *Id.* at 19619-620.

¹¹² *Id.* at 19620.

¹¹³ 42 C.F.R. § 425.7(d)(5) (proposed Apr. 7, 2011).

¹¹⁴ 76 Fed. Reg. at 19620.

¹¹⁵ 42 C.F.R. § 425.10(d)(4).

¹¹⁶ *Id.*

¹¹⁷ 42 C.F.R. § 425.7(d)(2)(i) (proposed Apr. 7, 2011).

¹¹⁸ *Id.* at § 425.7(d)(6).

¹¹⁹ *Id.*

¹²⁰ Physician-driven ACOs, rural ACOs and ACOs caring for underserved populations would be eligible for sharing in savings on a first-dollar basis under the one-sided model.

¹²¹ 42 C.F.R. § 425.7(d)(5).

¹²² 76 Fed. Reg. at 19621.

¹²³ 42 C.F.R. § 425.7(d)(8) (proposed Apr. 7, 2011).

¹²⁴ A PricewaterhouseCoopers study found that shared savings may not be much higher for Track 2, even though shared losses may be much greater; see, PricewaterhouseCoopers LLP, “Stalking the ACO Unicorn: What the proposed regulations for Accountable Care Organizations (ACOs) mean,” April 2011.

¹²⁵ *Id.* at § 425.7(9).

¹²⁶ *Id.* at § 425.5(d)(6)(iii).

¹²⁷ *Id.* at § 425.5(d)(6)(iv).

¹²⁸ Such an arrangement may raise Stark and anti-kickback concerns to the extent there is remuneration between referral sources and those seeking referrals. 76 Fed. Reg. at 19622.

¹²⁹ *Id.* at 19623.

¹³⁰ 42 C.F.R. § 425.5(6)(v) (proposed Apr. 7, 2011).

¹³¹ *Id.* at § 425.5(6)(vi).

¹³² *Id.* at § 425.5(6)(v).

¹³³ 76 Fed. Reg. at 19623.

¹³⁴ *Id.*

¹³⁵ *Id.*

¹³⁶ *Id.* at 19623-624.

¹³⁷ *Id.* at 19624.

¹³⁸ 42 C.F.R. § 425.5(d)(12)(i).

¹³⁹ *Id.* at § 425.5(d)(12)(ii).

¹⁴⁰ *Id.*

¹⁴¹ 76 Fed. Reg. at 19618.

¹⁴² *Id.* at 19624.

¹⁴³ Created by ACA, Pub. L. No. 111-148, § 3022 (Mar. 23, 2010).

¹⁴⁴ *Id.* at 19618.

¹⁴⁵ <http://www.gpo.gov/fdsys/pkg/FR-2011-04-07/pdf/2011-7884.pdf>.

¹⁴⁶ <http://www.ftc.gov/os/fedreg/2011/03/110331acofrn.pdf>.

¹⁴⁷ CAHPS is an acronym for Consumer Assessment of Health Providers and Systems.

¹⁴⁸ CLABSI is an acronym for Central Line-Associated Bloodstream Infections.