

Medicare Shared Savings Program Final Rule: Where Do We Go from Here?

December 22, 2011

McDermott Will & Emery is pleased to provide this supplemental matrix to its original *White Paper* summarizing and evaluating the Centers for Medicare & Medicaid Services (CMS) proposed Medicare Shared Savings Program (MSSP) regulations. As did the original *White Paper*, the matrix that follows provides both a summary of, and commentary on, CMS's published final regulations. The matrix, which is intended to be read together with the original *White Paper*, "[The Controversial Draft Medicare ACO Regulations: Analysis, Comments and Recommended Action](#)," includes specific cross-references (by page) to the original *White Paper*, identifying changes made from the Proposed Rule to the Final Rule, as well as McDermott's commentary and recommended action items. Readers should consult both the *White Paper* and the updated matrix when navigating through the Final Rule's requirements.

The overwhelming consensus among McDermott lawyers evaluating the Proposed Rule was that it lacked significant financial incentives for providers, and that the regulatory burdens were too high and often too ambiguous. Additionally, the proposed rule suffered from a misplaced focus on the macro level. For example, in the proposed rule, CMS focused on telling potential contractors "how" their accountable care organization (ACO) should be structured and governed, rather than setting forth parameters for "what" the contracting organization must be able to do or demonstrate in order to qualify for a contract with CMS. Rigidity, not flexibility or innovation, characterized the Proposed Rule.

The Final Rule, by comparison, deserves a more welcoming reception. The differences between the Proposed Rule and the Final Rule are encouraging and testify to CMS's efforts to listen and respond to the industry's comments and criticisms. Overall, the Final Rule improves the MSSP with more financial incentives and fewer barriers to participation, while preserving the overarching goals of improving the quality and cost-effectiveness of health care furnished under the Medicare Program.

From a practical perspective, the considerations relevant to an entity that is contemplating forming or joining an ACO have not materially changed under the Final Rule. Each entity, alone and in conjunction with its proposed ACO partners, must analyze the following:

- The action needed to form an ACO and to generate savings under the MSSP
- The financial and other costs that will be incurred in the process
- The short- and long-term benefits, financially and reputationally, to be derived from participation
- How the interests of the engaged patient population will be advanced

We hope that you find this update and the original *White Paper* to be a useful and valuable resource and strategic planning tool as you evaluate your organization's participation in the MSSP.

The authors and editors of these documents, as well as other McDermott lawyers with substantial experience and knowledge in the many issues raised by the MSSP, are available to respond to your questions and to facilitate your consideration and pursuit of shared savings programs.

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To learn more about accountable care organizations, visit McDermott's ACO Resource Center at <http://mwe.com/aco/>.

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	White Paper Cross-Reference	Changes from Proposed Regulations	McDermott Commentary	Action Items
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Section II – A. ELIGIBILITY AND GOVERNANCE

1. ELIGIBLE ENTITIES	Page 2	The list of entities eligible to form ACOs has been expanded to include FQHCs and RHCs. In this regard, the beneficiary assignment provisions have been modified so that primary care services provided by FQHCs and RHCs can be counted for attribution purposes.		
2. LEGAL STRUCTURE AND GOVERNANCE	Page 2			
a. <i>Legal Entity</i>	Pages 2–4	An ACO can include an entity formed under federal or tribal law.		
b. <i>Governance</i>	Page 4	<p>An ACO is not required to have proportionate representation on its governing board that includes a representative of every ACO participant. It is sufficient that ACO participants or their representatives have meaningful participation in the composition and control of the ACO’s governing body.</p> <p>CMS has created a limited exception to the requirements that (1) 75 percent of an ACO’s governing board be composed of ACO participants or their representatives, and (2) an ACO’s governing board include a beneficiary representative. In such cases, the ACO must explain why it seeks to differ from the standard requirements and how the ACO will involve ACO participants and</p>	<p>This is a significant improvement, since it will avoid the necessity of maintaining large and unwieldy boards.</p> <p>CMS will not prescribe the form that such “meaningful” participation must take.</p> <p>Reasons for deviating from the standard requirements could include, without limitation, impediments under state law (e.g., statutory requirements for the composition of public hospital boards, corporate practice of medicine restrictions) or the desire to include beneficiaries with a greater than 25 percent share of governance.</p>	

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		beneficiaries in innovative ways and provide for meaningful participation in ACO governance.		
3. LEADERSHIP AND MANAGEMENT	Page 4	An ACO's medical director may be part-time but must be one of the ACO's physicians. An ACL is not required to have a physician-directed quality assurance and process improvement committee. However, an ACO must describe how it will establish and maintain quality assurance and improvement programs, led by a qualified health care professional.	These changes decrease the burdens on small or rural ACOs in particular.	
4. ACCOUNTABILITY FOR BENEFICIARIES	Page 5			
5. AGREEMENT REQUIREMENT	Page 6	A three-year term is retained for ACOs approved for participation after 2012. For ACOs approved for participation in 2012, the start dates will be either April 1, 2012 (with a term of three years and nine months), or July 1, 2012 (with a term of three years and six months). The performance year for each ACO will be measured from January 1 of that year, with the exception of ACOs approved for participation in 2012, which will have an initial performance year measured from the start date through the end of 2013 (21 months and 18 months, respectively).	While ACOs approved for 2012 will have the benefit of six to nine months of participation beyond the standard three-year term, the initial performance year is measured by the entire 18- or 21-month performance, so there is no ramp-up or grace period for these early adopters.	

	<i>White Paper</i> Cross-Reference	Changes from Proposed Regulations	McDermott Commentary	Action Items
6. DISTRIBUTION OF SAVINGS	Page 6			
7. SUFFICIENT NUMBER OF PRIMARY CARE PROVIDERS AND BENEFICIARIES	Page 7			
8. PROCESSES TO PROMOTE EVIDENCE-BASED MEDICINE, PATIENT ENGAGEMENT, REPORTING AND COORDINATION OF CARE	Page 7			
a. <i>Processes to Promote Evidence-Based Medicine</i>	Page 8	<p>The Proposed Rule's general definition of evidence-based medicine as the application of the best available evidence gained from the scientific method to clinical decision-making is retained.</p> <p>The Final Rule expands on the Proposed Rule by requiring that an ACO define, establish, implement, evaluate and periodically update processes to accomplish evidence-based medicine (the Proposed Rule provided that an ACO, in its MSSP application, must provide CMS with documentation of its plan to promote these processes).</p> <p>The Final Rule expands on the Proposed Rule by requiring that an ACO's evidence-based medicine processes must cover diagnoses with significant potential for the ACO to achieve quality</p>	It is unclear what constitutes "significant potential" and whether an ACO's good faith belief at the outset will be sufficient if such quality improvements are not achieved for these diagnoses.	An ACO must understand its "baseline" patient population in the context of the ACO's own capabilities in order to identify diagnoses where outcomes have significant potential for improvement.

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b. <i>Processes to Promote Patient Engagement</i>	Page 7	improvements taking into account the circumstances of individual beneficiaries.		
c. <i>Processes to Report on Quality and Cost Measures</i>	Page 8	The Final Rule expands on the Proposed Rule by requiring an ACO to develop an infrastructure for its participants and providers/suppliers to internally report on quality and cost metrics, which enables the ACO to monitor, provide feedback and evaluate its ACO participants' and ACO provider(s)/supplier(s)' performance and to use these results to improve care over time.	While there is little guidance regarding the specific infrastructure required for this type of reporting, an ACO will need to develop policies and procedures that encourage and/or require its participants and providers/suppliers to provide this feedback in a useable way that allows the ACO to evaluate its and their performance and identify areas to improve.	
d. <i>Processes to Promote Coordination of Care</i>	Pages 8–9			

	<i>White Paper Cross-Reference</i>	Changes from Proposed Regulations	McDermott Commentary	Action Items
9. PATIENT-CENTEREDNESS CRITERIA	Pages 9–10	The ACO is required to 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, and to have a defined process to meet this requirement. ¹	There were few substantive changes. CMS removed some of the details from the Proposed Rule, such as an express requirement that providers enrolled in the electronic exchange of information make this process consistent with the EHR meaningful use requirements. The changes allow ACOs more flexibility. NB: The EHR reference was removed from the patient-centered criteria Final Rule and moved to the quality metrics section.	
a. <i>Beneficiary Experience of Care Survey</i>	Page 10	The ACO is required to select a CMS-certified vendor to administer the survey and report the results for performance years beginning in 2014 and for subsequent performance years. ²	ACOs approved for 2012 will have a greater opportunity for internal assessment and opportunities to improve prior to the collection of data and commencement of the reporting requirement.	
b. <i>Patient Involvement in Governance</i>	Page 10	There are no material changes from the Proposed Rule, except that ACOs that have stakeholder organizations serving on their governing body will be deemed to have satisfied the requirement of having stakeholder participation.		

¹ 42 CFR § 425.112(a)(ii).

² 42 CFR § 425.500(d).

	White Paper Cross-Reference	Changes from Proposed Regulations	McDermott Commentary	Action Items
c. <i>Evaluation of Population Health Needs and Consideration of Diversity</i>	Page 11			
d. <i>Implementation of Individualized Care Plans and Integration of Community Resources</i>	Page 11			
10. ACO MARKETING GUIDELINES	Pages 11–12	<p>CMS revised the definition of marketing materials to include social media, such as Facebook and Twitter.</p> <p>CMS also revised the regulations governing the marketing guidelines to include a “file and use” process. Under the file and use process, marketing materials that are submitted to CMS and certified by the ACO that they are in compliance with the CMS marketing guidelines are “deemed” approved. Therefore, ACOs may begin using marketing materials that they submit and certify to CMS five days after they have been submitted. CMS will provide model language for ACOs to use for various marketing materials.</p> <p>In addition, CMS included new sanction authority in the Final Rule to clarify that ACOs that do not comply with the marketing guidelines will be subject to sanctions.</p>	<p>CMS reiterated its concern that marketing activities present opportunities to mislead beneficiaries. ACOs should expect CMS to monitor and scrutinize marketing activities. CMS will issue additional marketing guidance and model language for use in marketing materials, and ACOs should make an effort to comply with that guidance.</p>	

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11. PROGRAM INTEGRITY REQUIREMENTS	Pages 11–12	<p>CMS clarified what it expects from an ACO's compliance plan.</p> <p>First, "in order to ensure independent and objective legal reviews and financial analyses of the organization's compliance efforts and activities by the compliance officer," an ACO's compliance officer cannot also be its legal counsel.</p> <p>CMS also amended the regulations to support its belief that all individuals and entities that perform functions or services related to ACO activities, not just ACO participants and ACO providers/suppliers, should have access to mechanisms that allow for anonymous reporting of suspected problems to the compliance officer.</p> <p>With respect to the standard that triggers mandatory reporting to an appropriate law enforcement agency, CMS changed the standard "suspected" to "probable" without any explanation.</p> <p>CMS refined the authorities governing an ACO's compliance program to require that the ACO periodically update the compliance program to reflect changes in law and regulations.</p>	<p>CMS reiterated its position that a compliance plan is an integral part of an ACO's organizational structure and function. ACO participants and ACO providers/suppliers that, as Medicare providers, currently operate under compliance plan requirements, will now be required to know and comply with additional obligations relating to their participation in an ACO, including training and education obligations.</p> <p>ACOs can expect that CMS will conduct monitoring and oversight of these compliance plan requirements, and should be prepared to demonstrate how the ACO's compliance plan prevents against fraud, waste and abuse in the MSSP.</p>	An ACO's compliance plan is an integral part of an ACO's formation. Organizations and entities forming an ACO should include in their discussions how the ACO will create and implement an effective compliance plan.

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Section II – B. THE START DATE FOR THE ACO AGREEMENT

1. EFFECT OF CHANGES THAT OCCUR DURING AN ACO AGREEMENT’S THREE-YEAR PERIOD	Page 13	<p>CMS modified the timing for enrollment in the MSSP. In CY 2012, an ACO will have the flexibility to begin participation in the MSSP either April 1 or July 1.</p> <p>CMS still considers participation to be for three performance years, although the length of time for the first performance year will differ based on the enrollment date. For those ACOs enrolling in the MSSP for participation beginning April 1, the first performance year will be 21 months, ending December 31, 2013. For those ACOs enrolling in the MSSP for participation beginning July 1, the first performance year will be 18 months, ending December 31, 2013. Thereafter, each performance year will begin January 1 and continue through December 31 of the same year.</p> <p>CMS also notes that eligible providers participating in an ACO that meets the quality standards but does not generate shared savings will nevertheless qualify for a PQRS incentive payment.</p>	<p>Although the first enrollment date, April 1, 2012, is only six months away, CMS has yet to release the application for participation in the MSSP.</p>	<p>Even without seeing the application, given the relatively short period of time ACOs will have to complete the application process for enrollment in the MSSP by April 1, 2012, ACOs interested in participating in the MSSP by that date should begin preparing for enrollment as soon as possible (<i>i.e.</i>, organize an ACO entity, comply with the governance requirements, create a system for reporting MSSP performance standards, implement EHR systems).</p> <p>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, other innovative payment models under ACA (<i>e.g.</i>, 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</p>
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				<p>infrastructure. In doing so, it is important to recognize that there is no “one size fits all” or risk-free approach.</p> <p>Evaluate the capacity and capability of the current health information infra-structure to support robust quality measurement, analytics and reporting, care coordination, and alignment of incentives under new payment and reimbursement models.</p> <p>Address the “build vs. buy” decisions early in the planning process by taking the following actions, among others:</p> <p>Explore opportunities to supplement internal electronic data capabilities and infra-structure, 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.</p> <p>Anticipate and explore opportunities to collaborate with other hospitals and health systems, state govern-ments, universities and others to leverage human and capital resources and to reduce the learning curve.</p>

	<i>White Paper Cross-Reference</i>	Changes from Proposed Regulations	McDermott Commentary	Action Items
a. <i>Program Changes by CMS</i>	Page 13	<p>CMS modified the Proposed Rule to permit an ACO to voluntarily terminate its agreement with CMS and therefore its participation in the MSSP in those instances where the ACO believes that the changes in the MSSP statutory and regulatory standards will affect its ability to continue to participate in the MSSP.</p> <p>However, the ACO must be aware that voluntary termination of its participation in the MSSP will result in the ACO becoming ineligible to share in any savings for the performance year in which the ACO provides CMS with its notice of termination. Otherwise, an ACO's termination from participation in the MSSP when affected by regulatory or statutory changes will be without penalty.</p>	<p>ACOs should take comfort in the fact that an ACO may terminate its participation in the MSSP if regulatory or statutory changes make continued participation onerous. Such termination may be advisable despite the forfeiture of accrued savings. That would be the case, of course, if the ACO exercised its voluntary termination right because of the incurrence of substantial losses.</p> <p>Forfeiture of accrued savings for voluntary early termination by the ACO differs from the approach CMS has taken in the terms and conditions of participation in the Pioneer ACO program, under which an ACO will forfeit accrued savings only in the event CMS terminates the agreement early due to breach by the Pioneer ACO.</p>	
b. <i>Other Changes</i>	Page 14	<p>CMS recognizes that during the term of the MSSP agreement, ACO participants and providers/suppliers may need to be added and/or subtracted from participation in the ACO, or that the ACO may undergo additional "significant changes" that may require adjustments to the ACO's bench mark or even make an ACO ineligible to participate in the MSSP. Accordingly, CMS has added to the Final Rule the ability for an ACO to notify CMS of the addition or subtraction of ACO</p>	<p>An ACO may have compelling reasons to add or subtract ACO participants and providers/suppliers during the ACO's participation in the MSSP. For example, in order to maintain the minimum number of ACO beneficiaries, an ACO may need to add or replace ACO participating primary care physicians. With this modification to the Final Rule, CMS no longer prohibits the ACO from making such changes, and doing so only</p>	

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		participants and providers/suppliers and of “significant changes” within 30 days of such changes. For certain “significant changes, CMS may decide to terminate the agreement with the ACO and terminate the ACO’s participation in the MSSP.	requires that the ACO notify CMS within 30 days of such changes.	
2. TIMING AND PROCESS FOR EVALUATING SHARED SAVINGS PERFORMANCE	Page 14	In the interest of providing ACOs with timely information relating to performance, CMS shortened the claims run-out period from six months to three months.	<p>The shorter run-out period means quicker shared savings payments.</p> <p>The shorter claims run-out period provides ACOs with an opportunity to delay submitting claims for certain high-cost procedures in order to maximize shared savings. However, ACO participants should remain mindful that taking advantage of this change may result in termination of the ACO’s participation in the MSSP.</p>	
3. DATA SHARING	Page 14			
a. <i>EHR Adoption as a Condition of Participation in the MSSP</i>	Pages 14–15	Although CMS continues to encourage the adoption of EHR, CMS substantially modified its approach to EHR adoption. CMS retained EHR adoption as a quality measure and weighted it twice that of other quality measures, but eliminated the meaningful use participation condition.	<p>Under the Proposed Rule, a condition of participation was the ability to demonstrate that, beginning in the second performance year, 50 percent of the ACO’s primary care providers are “meaningful users” of EHR.</p> <p>CMS explained that this modification is intended to better align the MSSP requirements for EHR meaningful use with the Medicaid EHR Incentive Program.</p>	Despite the elimination of the EHR condition, providers should accelerate EHR system implementation and integration in both the inpatient and ambulatory care settings. This will position them ultimately to meet their own data collection and analysis. The commentary to the Final Rule reiterates CMS’s expectation that ACOs ultimately will establish such self-sufficiency.

	<i>White Paper Cross-Reference</i>	Changes from Proposed Regulations	McDermott Commentary	Action Items
b. <i>Types of Data Sharing</i>	Page 15	Under the Final Rule, CMS will provide ACOs with a list of preliminarily, prospectively assigned beneficiaries.	<p>The change also suggests recognition by CMS that achieving EHR meaningful use for some providers will be difficult or perhaps impossible.</p> <p>As in the proposed rule, under the Final Rule CMS will provide the ACO aggregate data reports, limited identifying information about beneficiaries whose information serves as the basis for the aggregate reports, and beneficiary-identifiable claims data.</p>	<p>Efforts to accelerate EHR implementation are supported under provisions of other current laws, such as the flexibility under federal fraud and abuse laws to donate EHR technology to physicians, the HITECH Act financial incentives for EHR meaningful use, and the federal funding of health information exchanges at regional and state-wide levels.</p> <p>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 term 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.</p>
i. FOUR SPECIFIC BENEFICIARY-IDENTIFIABLE DATA ELEMENTS	Page 15	CMS modified its proposal to add that CMS will also provide this information with each quarterly aggregated report.	<p>CMS suggests that an ACO use the four specific beneficiary-identifiable data elements CMS provided to identify prospective ACO beneficiaries, review their records and identify care coordination processes that may need to be changed.</p> <p>CMS further suggests that the</p>	

	<i>White Paper</i> Cross-Reference	Changes from Proposed Regulations	McDermott Commentary	Action Items
ii. BENEFICIARY-IDENTIFIABLE CLAIMS DATA	Pages 15–17	The Final Rule includes an expanded list of claims-related data elements applicable to Medicare Parts A, B and D that an	<p>ACO could use this information to reach out to beneficiaries to notify them of the ACO's participation in the MSSP and of the opportunity to opt out of data sharing. Using this approach, if neither the ACO nor CMS receives notice from the beneficiary declining data sharing, the ACO could then request beneficiary-identifiable data. However, CMS indicated that the ACO would have to provide the beneficiary with notice and the opportunity to decline data sharing again during the next face-to-face appointment. Therefore, an ACO may not find it advantageous to take the opportunity to notify beneficiaries of their opt-out opportunity prior to that appointment unless the ACO believes it will enhance beneficiaries' comfort level in granting the permission and/or the beneficiaries' awareness of the ACO and what its providers have to offer.</p> <p>It is important to note that even where a beneficiary declines data sharing, ACO participating providers may still share medical record information as allowed under HIPAA.</p> <p>CMS emphasized that this expanded list was included only as an example of the beneficiary-identifiable data</p>	Prepare the signage and written notices necessary to explain to beneficiaries the possibility that CMS may

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iii. AGGREGATED DATA REPORTS	Page 17	<p>ACO may request CMS to provide.</p> <p>The comments to the Final Rule confirm that an ACO may request, but will not be required to provide, information as often as each month.</p>	<p>elements that may be available to the ACO and is not intended to limit or prohibit an ACO from requesting all “minimum necessary” data elements available from CMS.</p> <p>CMS did not provide any detail on the specific types of aggregate reports and/or the data that will be used in</p>	<p>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 (1) be provided with enough advance notice to make the opt-out decision; (2) provide adequate information about how the information will be shared and used, and the benefits and risks of making data available for the proposed uses; (3) not be coercive; and (4) 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.</p> <p>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 Data Use Agreement.</p>

	<i>White Paper</i> Cross-Reference	Changes from Proposed Regulations	McDermott Commentary	Action Items
iv. OVERALL ACO DATA STRATEGY AND INFRASTRUCTURE			<p>preparing the aggregate reports except to indicate that the aggregate reports will include information on the financial performance, quality performance scores, aggregated beneficiary population metrics and beneficiary utilization data.</p> <p>Although aggregated reports are de-identified, CMS will provide the four specific beneficiary-identifiable data elements discussed for each of the individuals whose information was used in the creation of the aggregated data reports.</p> <p>CMS left open the door to consider including within the aggregated data reports regional or national ACO data for comparison.</p> <p>The Final Rule does not address whether an ACO can retain copies of the data CMS provides after the ACO terminates its participation in the MSSP or whether the ACO may use CMS-provided data for other purposes within and outside of the ACO.</p> <p>Unless the Data Use Agreement CMS develops for use in the MSSP addresses this important consideration, the Final Rule may fall short of fulfilling the CMS's stated expectation that ACOs should use, aggregate</p>	<p>At a minimum, an ACO should determine when and to what extent it will need CMS beneficiary-identifiable 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.</p> <p>Consider the prospects under any data strategy for leveraging the infrastructure and resources to develop</p>

	<i>White Paper</i> Cross-Reference	Changes from Proposed Regulations	McDermott Commentary	Action Items
			and combine CMS data to provider-level data and data internally generated and compiled within an ACO in order to enable the ACO to develop a more complete picture of the care that its beneficiary population receives within and outside of the ACO, and also of its participating providers' patterns of care. Such data aggregation will also enable an ACO to compare its current year performance with that of the previous years under the program.	robust information repositories that will support innovations in the delivery of care (including personalized medicine) and payment mechanisms not only now but also well into the future.
4. LEGAL AUTHORITY FOR CMS SHARING OF BENEFICIARY- IDENTIFIABLE DATA	Page 17		<p>CMS emphasized that there are a number of issues and sensitivities surrounding the disclosure of individually identifiable health information, and that a number of laws place constraints on the sharing of individually identifiable health information.</p> <p>Accordingly, CMS confirmed that its decision to share aggregated data reports and to share those specific beneficiary-identifiable data elements discussed above was made only after CMS validated that doing so would be in compliance with applicable legal limitations and policy considerations.</p>	Analyze the federal and state privacy and security law risks related to sharing between and among ACO participants of identifiable data that is either provided by CMS or internally generated within the ACO.
a. <i>HIPAA Compliance</i>	Pages 17–18		The ACO's participants and ACO providers/suppliers are all HIPAA-covered entities. The ACO would at times be both a	

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			<p>covered entity (if it is a provider of health care services and engages in HIPAA-covered electronic transactions) and a business associate of the ACO participants and the ACO providers/suppliers.</p> <p>As covered entities or business associates of a covered entity, the ACO, the ACO participants and the ACO providers/suppliers would be permitted under HIPAA to receive and use beneficiary-identifiable information (<i>i.e.</i>, protected health information) to carry out health care operations on their behalf.</p> <p>Finally, CMS and the ACO (if a provider), and CMS and each of the ACO participants and the ACO providers/suppliers, have had a “relationship” with the beneficiaries whose identifiable claims information is being shared, and the disclosure of the data by CMS pertains to that relationship.</p> <p>Accordingly, HIPAA permits an ACO to request CMS to disclose beneficiary-identifiable 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, as long as the information provided is the</p>	

	<i>White Paper Cross-Reference</i>	Changes from Proposed Regulations	McDermott Commentary	Action Items
b. <i>Compliance with Federal Substance Abuse Program Records Laws</i>	Page 18	CMS will not share claims data relating to alcohol and substance abuse treatment.	minimum data necessary to accomplish the MSSP goals of the ACO.	
c. <i>Privacy Act Compliance</i>	Page 18		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. <i>Part D Data Rule</i>	Pages 18–19		As seen in the Proposed Rule, the Final Rule appears 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.	

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Section II – C. ASSIGNMENT OF MEDICARE FEE-FOR-SERVICE BENEFICIARIES

1. DEFINITION OF ACO FOR PURPOSES OF BENEFICIARY ASSIGNMENT	Pages 19–20			
2. DEFINITION OF PRIMARY CARE SERVICES	Page 20	<p>The Final Rule expanded the list of codes constituting primary care to include the “Welcome to Medicare” visit (HCPCS code G0402) and the annual wellness visits (HCPCS codes G0438 and G0439).</p> <p>The Proposed Rule discussed three potential approaches to defining “primary care services” for purposes of beneficiary assignment. The first approach was assignment based on a defined set of “services,” regardless of the type of provider furnishing such services. The second approach was 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 was 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 Rule adopted the second approach.</p>	<p>CMS acknowledged that the final list of codes is an “approximation” of primary care services and intends to monitor this issue going forward.</p> <p>Ultimately, CMS concluded that the step-wise approach maintains a primary-care-centric approach, which recognizes the fact that specialists (especially in certain areas) play a role in the delivery of primary care.</p>	<p>Analyze the list of primary care codes in the Final Rule to determine if the final list of codes could have an unexpected impact on beneficiary assignment (either by inclusion or exclusion of codes).</p> <p>Providers should assess the impact of this change on potential beneficiary assignment. Especially in areas with a shortage of traditional primary care providers, this change could have a material impact on beneficiary assignment.</p> <p>The requirement that the TINs under which the services of specialists are included in the assignment process be exclusive to a single ACO could result in significant competition among ACOs for alignment of specialists.</p>

	<i>White Paper</i> Cross-Reference	Changes from Proposed Regulations	McDermott Commentary	Action Items
		<p>However, the Final Rule adopted the third, step-wise approach. As discussed above, under this approach beneficiaries who are not seeing a primary care physician may be assigned to an ACO on the basis of primary care services provided by a specialist. Notably, the TINs under which the services of specialists are included in the assignment process would have to be exclusive to a single ACO. In the second step of the step-wise approach, the ACO that provides the plurality of services will be determined by reference to the primary care services provided by specialist physicians and services provided by other ACO professionals (e.g., NPs and PAs).</p> <p>In addition, the Final Rule clarifies that if a Medicare beneficiary receives the plurality of primary care services from a non-ACO provider, such beneficiary will not be assigned to an ACO, even if such beneficiary receives some primary care service from an ACO physician.</p> <p>The Final Rule also modifies the Proposed Rule in a manner that permits beneficiary assignment based on primary care services furnished by a FQHC or RHC.</p>		

	<i>White Paper</i> Cross-Reference	Changes from Proposed Regulations	McDermott Commentary	Action Items
3. PROSPECTIVE VERSUS RETROSPECTIVE BENEFICIARY ASSIGNMENT	Page 20	CMS revised its approach to provide for prospective assignment of beneficiaries to ACOs in a preliminary manner, with final assignment determined retrospectively.	The Final Rule suggests that the new approach is more prospective in nature. In actuality, for purposes of shared savings and losses, beneficiary assignment is retrospective in nature. The Final Rule provides more regular and timely information to ACOs regarding beneficiary alignment. In the final analysis, however, beneficiary assignment for purposes of shared savings and losses is retrospective.	
4. MAJORITY VERSUS PLURALITY RULE FOR BENEFICIARY ASSIGNMENT	Page 20			
5. BENEFICIARY INFORMATION AND NOTIFICATION	Pages 20–21	The Final Rule makes two material modifications. First, an ACO may provide notification of its participation to beneficiaries who appear on the preliminary prospective assignment lists. Second, to minimize beneficiary confusion, an ACO does not need to provide notice to beneficiaries if the ACO does not renew its ACO agreement or if the ACO agreement is terminated.	Presumably, CMS was concerned about potential confusion regarding ceasing to be an ACO, on the one hand, and ceasing to participate in Medicare, on the other hand.	

	<i>White Paper</i> Cross-Reference	Changes from Proposed Regulations	McDermott Commentary	Action Items
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Section II – D. Section II. - D. QUALITY AND OTHER REPORTING REQUIREMENTS

1. INTRODUCTION	Page 21			
2. PROPOSED MEASURES TO ASSESS THE QUALITY OF CARE FURNISHED BY AN ACO	Pages 21–22	<p>In the Final Rule, there will be 33 measures sorted into four domains. Two of the proposed domains, Care Coordination and Patient Safety, have been consolidated into a single domain.</p> <p>An ACO will continue to meet the quality performance standard for Year One through complete and accurate measures reporting. In Year Two, a portion of the measures will be transitioned to pay for performance. In Year Three, all but one of the measures will become pay for performance.</p>	<p>CMS has explained that the combination of the Care Coordination and Patient Safety domains better aligns with other CMS value-based purchasing initiatives and underscores the importance of ambulatory patient safety and care coordination.</p> <p>In Year Three, one of the measures—CAHPS: Health Status/Functional Status in the Patient/Caregiver Experience domain—will not transition to pay for performance and will remain pay for reporting. It is unclear when/if that will happen.</p>	
3. REQUIREMENTS FOR QUALITY MEASURES DATA SUBMISSION BY ACOS	Pages 22–23	<p>Seven measures will be collected through patient surveying, three through claims, one through EHR Incentive Program Data and 22 through ACO GPRO.</p>	<p>For the patient/caregiver experience measures, in 2012 and 2013 CMS will fund a survey to better compare ACOs' performances over time. Starting in 2014, ACOs must select a survey vendor approved by CMS and fund the cost of administering this survey themselves.</p>	

	<i>White Paper Cross-Reference</i>	Changes from Proposed Regulations	McDermott Commentary	Action Items
4. QUALITY PERFORMANCE STANDARDS	Page 23			
a. <i>Measuring Quality Performance</i>	Page 23	There will be 33 measures sorted into four domains. These 33 measures have been further narrowed into 23 scored measures, since the patient experience survey measures, all-or-nothing measures and coronary artery disease measures will be scored as one measure each.	<p>CMS explained it removed “operationally complex,” “redundant and “burdensome” measures. The current set of measures, however, is not final. As CMS notes, these measures are a “starting point” and will be modified in future reporting cycles. ACOs are required to comply with any measures updates.</p> <p>Most of the measures that have been eliminated are from the Proposed Rule’s Care Coordination, Patient Safety and At-Risk Population/Frail Elderly Health (now termed At-Risk Population).</p>	
b. <i>Methods for Establishing Quality</i>	Page 23			
c. <i>Performance Scoring</i>	Pages 24–26	Each domain will be weighted at 25 percent in calculating an ACO’s overall quality performance. One of the measures—Percent of PCPs who Successfully Qualify for an EHR Incentive Payment—will be double-weighted (four maximum points instead of two). ACOs are also required to achieve the quality performance standard on 70 percent of the measures in each domain. If the ACO fails to meet this 70 percent benchmark for all four domains, it will be given a warning, and if the ACO continues to underperform, its participation in	Based on the 70 percent requirement, an ACO could fail one or more individual measures in a domain and still earn shared savings. If an ACO, however, does not properly report the EHR measure, it will fail to reach 70 percent in the Care Coordination domain (since the EHR measure is double-weighted) and thus fail to meet its 70 percent goal for all four domains.	

	<i>White Paper</i> Cross-Reference	Changes from Proposed Regulations	McDermott Commentary	Action Items
d. <i>Quality Threshold</i>	Page 26	the MSSP will be terminated. This approach will not be used to calculate the quality performance standard. Rather, the Performance Scoring option has been adopted for the final rule.		
5. INCORPORATION OF OTHER REPORTING REQUIREMENTS RELATED TO THE PQRS AND HER TECHNOLOGY UNDER SECTION 1848 OF ACA	Pages 26–27	The PQRS payment will be conditioned on satisfactory reporting of the 22 ACO GPRO measures only. The payment is not contingent on proper reporting of the measures collected through non-GPRO routes (such as through claims data). In addition, the Final Rule does not require that 50 percent of PCPs become “meaningful EHR users” by the start of the second performance year in order to continue participation in the MSSP.	CMS’s changes are intended to streamline reporting and reduce administrative burden.	
6. PUBLIC REPORTING	Page 27	In the Proposed Rule, it was unclear where the information would be reported and how it would be made public. In the Final Rule, ACOs must “publicly report” the required information. ³	It is still unclear how ACOs will “publicly report” the required information.	
7. ALIGNING ACO QUALITY MEASURES WITH OTHER LAWS AND REGULATIONS	Pages 27–28			

³ 42 C.F.R. § 425.308.

	White Paper Cross-Reference	Changes from Proposed Regulations	McDermott Commentary	Action Items
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Section II – E. SHARED SAVINGS DETERMINATIONS

1. OVERVIEW OF THE ONE-SIDED AND TWO-SIDED FINANCIAL PERFORMANCE MODELS	Page 28	<p>CMS retained the two-track models, but eliminates the Track One downside risk sharing in performance year three of the three-year agreement</p> <p>CMS incorporated a series of other modifications to increase availability of funds during the three-year term, including the following:</p> <p>Elimination of 25 percent withhold for both tracks</p> <p>Three-month, rather than six-month, claims run-out period for performance evaluation</p> <p>First-dollar savings for both tracks</p> <p>Interim payments may be available to ACOs under both tracks. The ACO's application will indicate election of such payments as well as the ACO's intended mechanism to repay any interim monies received if the ACO actually experiences losses during the performance year.</p> <p>Failure to achieve net savings during the first agreement does not automatically preclude participation under a second agreement.</p>	<p>Conversion of the Track One Model to an "Up-Side Only" model is intended to encourage participation by certain groups—e.g., small and medium-sized physician practices, rural ACOs—that may not have any experience with care management or managing performance-based risk, or may have hesitation regarding the up-front investment in light of potential for downside risk.</p> <p>As the absence of downside risk may not initiate the significant change in delivering health care envisioned for the MSSP, ACOs may only elect Track One for the initial three-year agreement. All subsequent agreements must use the Track Two Model.</p>	<p>CMS's revised approach to the Track One Model as well as other modifications to the financial components are an effort to respond to industry comments to the Proposed Rule (particularly the high cost/low reward nature of the models) and to increase the potential financial benefits for smaller ACOs and entities new to managing performance-based on risk. CMS noted that "Commenters explained that financial rewards must be sufficient to offset provider risks and startup-costs." According to one commenter "the program [as proposed] placed inordinate investment pressure on medical providers for an insufficient return that carries a significant amount of risk, regardless of the type of ACO."⁴</p> <p>Although every organization will need to evaluate the financial implications of participation, CMS's changes</p>
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⁴ Final Rule at p. 402.

	<i>White Paper</i> Cross-Reference	Changes from Proposed Regulations	McDermott Commentary	Action Items
				may create new opportunities for (or at least change dynamics of) MSSP participation for providers that may have previously written it off.
2. CALCULATING THE BENCHMARK FOR THE PERFORMANCE YEARS	Pages 28–29	<p>The steps for determining the benchmark remain unchanged, although CMS made modifications to the individual components that comprise the benchmark. Examples include the following:</p> <ul style="list-style-type: none"> • CMS will calculate the payment amounts for Part A/B services for beneficiaries that would have been assigned to the ACO in any of the three years prior to the agreement period (benchmark years). Under the Final Rule, CMS will take “a categorical approach,” calculating expenditure for four population categories—ESRD, disabled, aged-in/non-dual, and aged-in duals—rather than using a single calculation for all of the beneficiaries whose data is used to determine the expenditures for a benchmark year. This change is intended to more accurately capture the costs (and expected expenditures) for each of these populations. A similar categorical approach will be used to update the benchmark for each performance year. • Under the Final Rule, Part A 	<p>The benchmark remains a data-driven threshold with no real opportunity to deviate.</p> <p>To the extent ACO participants are able to develop a statistically valid data set, it may be feasible to calculate a rough estimate of a potential benchmark in advance of entering into an agreement with CMS.</p>	

	<i>White Paper Cross-Reference</i>	Changes from Proposed Regulations	McDermott Commentary	Action Items
a. <i>Per Capita Expenditures</i>	Page 29	<p>and Part B expenditures that make up the benchmark are exclusive of IME and DSH payments.</p> <p>Expenditures used to calculate the benchmark will be adjusted to reflect the health status of the benchmark population using the CMS-HCC system. Under the Final Rule, CMS now will update the adjustment, and thus the benchmark, for each performance year in order to capture changes in the population’s health status.</p>	<p>Selection of beneficiaries for purposes of calculating an ACO’s benchmark will use the same methodology as beneficiary assignment for each performance year.</p>	
3. OTHER PAYMENT-RELATED ADJUSTMENTS	Page 29	<p>Rather than capping growth in risk adjustment between performance years, CMS will incorporate into an ACO’s updated benchmark for each performance year (1) an update to the ACO’s prospective CMS-HCC risk scores, reflecting the severity and case mix for newly assigned beneficiaries, and (2) updated demographic factors to adjust for severity and case mix of continuously assigned population (whether such update results in an increase or decrease in the risk score for the population).⁵</p>	<p>CMS finalized its proposal to monitor and audit ACOs’ coding practices because of their financial implications for ACO benchmarks and risk scores.</p> <p>ACOs may consider requiring ACO providers and suppliers (in addition to ACO participants) to submit certifications as to the accuracy of their coding practices as part of a condition of participating in the ACO.</p> <p>ACOs also might consider developing processes and</p>	

⁵ 42 C.F.R. § 425.604(a).

	White Paper Cross-Reference	Changes from Proposed Regulations	McDermott Commentary	Action Items
a. <i>IME and DSH Payments Retained in Benchmark Calculation</i>	Page 29	CMS will exclude IME and DSH payments from both the benchmark and performance calculations to eliminate a possible incentive for ACOs to avoid referrals to teaching hospitals.	<p>protocols by which they evaluate internal data for assigned beneficiaries in order to validate data relating to individuals, particularly for individuals with a high risk profile or for whom the data shows a significant (upward) change in codes, both groups which CMS likely would target in any audit.</p> <p>This change is another example of CMS's efforts to align the benchmark and performance year data analysis and calculations in a manner that seeks to meet the dual needs of protecting Medicare beneficiaries' access to care and providing mechanisms that promote effective and efficient care delivery to generate aggregate savings.</p>	
b. <i>Geographic Payment Adjustments Retained in Benchmark Calculation</i>	Page 29			
c. <i>Certain Bonus Payments and Penalties Excluded</i>	Pages 29–30			
d. <i>Accounting for Growth Trend</i>	Page 30			
e. <i>Adjustments for Beneficiary Characteristics</i>	Page 30	CMS introduced a more beneficiary-specific methodology for calculating payment amounts	This change is intended to account for differences in disease severity and resulting	

	<i>White Paper Cross-Reference</i>	Changes from Proposed Regulations	McDermott Commentary	Action Items
f. <i>Trending Forward – Risk – and Growth-Adjusted Benchmark Years</i>	Page 30	<p>for Parts A and B data that includes categorizing beneficiaries into one of four groups (ESRD, disabled, age-in/dual eligible, age-in/non-dual) to more accurately capture the case mix, severity and costs of beneficiaries.⁶</p> <p>Consistent with other components of the benchmark determination, CMS will trend the benchmark forward using costs for each of the four categories of beneficiaries (ESRD, disability, age-in/duals, age-in/non-duals) to enhance the accuracy of the benchmark.</p> <p>CMS introduced a new concept of modifying a performance year's benchmark to reflect health status for newly assigned beneficiaries and changes to demographic factors of continuously assigned beneficiaries, incorporating the expenditures for the four categories of beneficiaries in these re-calculations.</p>	<p>cost differentials within the Medicare population.</p> <p>Both modifications are intended to more accurately capture cost variations within the Medicare population so that actual expenditures (and any resulting savings) can be determined with greater precision and so that “normal fluctuations” in case mix do not arbitrarily help or hurt an ACO's performance.</p>	
g. <i>Weighting the Benchmark Years</i>	Pages 30–31			
h. <i>Benchmark for Future Performance Years</i>	Page 31	The benchmark update will reflect expenditure calculations for the four categories of beneficiaries. ⁷		

⁶ 42 C.F.R. § 425.602(a)(2).

⁷ 42 C.F.R. § 425.602(b).

	White Paper Cross-Reference	Changes from Proposed Regulations	McDermott Commentary	Action Items
i. <i>Option Two – The Road Not Taken</i>	Page 31	<p>This option establishes an ACO’s benchmark based on Parts A and B expenditures in each of the three benchmark years for each individual assigned to the ACO during the performance years</p> <p>CMS did not adopt this option for the MSSP; rather, CMS will monitor the Pioneer ACO program, which will use a methodology similar to this option.</p>		
4. MINIMUM SAVINGS RATE	Pages 31–32	<p>ACOs must meet or exceed the MSR (in addition to other performance requirements) in order to share in any savings generated).</p> <p>CMS eliminated the 2 percent net savings requirement, permitting first-dollar sharing once the MSR is met/exceeded.</p>	<p>Elimination of the 2 percent net savings requirement maximizes an ACO’s potential for shared savings. CMS again demonstrates its desire to eliminate barriers to MSSP participation.</p> <p>The challenges for smaller ACOs operating on Track One, which must achieve a higher savings rate (e.g., 3.9 percent), remain unchanged.</p>	
5. SHARING RATE ADD-ONS	Page 32	<p>CMS eliminated shared savings add-ons for FQHC and RHC participation in light of the decision to permit these facilities to be ACO participants</p> <p>The maximum sharing rate thus will be directly linked to the quality score, and the maximum savings rate remains at 50 percent.</p>		

	<i>White Paper Cross-Reference</i>	Changes from Proposed Regulations	McDermott Commentary	Action Items
6. DETERMINING THE FINAL PAYMENT AMOUNT	Page 32			
a. <i>Performance Payment Limit</i>	Page 32	CMS increased the performance payment limit from 7.5 to 10 percent of the ACO's benchmark.	<p>This change, coupled with elimination of the net 2 percent savings requirement, reflects a significantly greater opportunity for financial benefit under Track One (and with no downside risk) as compared to the Proposed Rule.</p> <p>It remains unclear whether the potential financial incentives (1) are enough to offset the necessary investment (including re-paying any interim payments received in performance years for which the ACO incurs a loss), and (2) whether the ACO is able to develop sufficient experience to be able to capitalize on the experience for a second term (or other accountable care-type arrangements).</p>	
b. <i>Withholds</i>	Pages 32–33	The 25 percent withhold is eliminated, consistent with the elimination of downside risk in performance year three.	To the extent a Track One ACO generates any shared savings during a performance year, elimination of the withhold increases the monies that an ACO may receive in the following year. This could enable ACO participants to infuse more capital investment into the ACO during the term of the arrangement and/or permit payments to reduce financial pressure on ACO participants making long-term capital investments.	

	White Paper Cross-Reference	Changes from Proposed Regulations	McDermott Commentary	Action Items
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Section II – F. TWO-SIDED MODEL

<p>1. SUMMARY OF THE TWO-SIDED MODEL</p>	<p>Page 33</p>	<p>ACOs participating in Track One no longer participate in the two-sided model during the third performance year, so the requirements of the two-sided model will only apply to ACOs choosing Track Two.</p> <p>ACOs experiencing a loss during the first agreement period are allowed to continue participating in the MSSP (both tracks).</p> <p>ACOs choosing to participate in Track One for the initial agreement period must participate in the Track Two model for the subsequent agreement.</p>	<p>Since the two-sided model only applies to ACOs choosing Track Two, the difference between the risks associated with choosing Track Two as opposed to Track One is relatively greater than when Track One participants also had to operate under the two-sided model. This reflects CMS's intent to make Track One less risky than Track Two, and ensure that the MSSP attracts less experienced and smaller ACOs.</p> <p>CMS's expressed goal in the Final Rule is to provide greater incentives for participation in the MSSP under both Tracks One and Two (e.g., first dollar shared savings) by enhancing the potential upside.</p>	<p>Entities should thoroughly evaluate whether to participate in Track One or Track Two given the greater disparity in the risk profile of each track.</p> <p>In light of the greater potential upside and incentives for participation, entities that may have written off the MSSP after the Proposed Rule may want to engage in a thorough analysis of whether to participate.</p>
<p>2. CMS'S PREFERENCE FOR TWO-SIDED RISK MODEL</p>	<p>Pages 33–34</p>			
<p>3. ELEMENTS OF THE TWO-SIDED MODEL</p> <p>a. <i>Beneficiary Notifications and Protections</i></p>	<p>Page 34</p> <p>Page 34</p>			

	<i>White Paper Cross-Reference</i>	Changes from Proposed Regulations	McDermott Commentary	Action Items
b. <i>ACO Eligibility Requirements</i>	Page 34	<p>CMS eliminated the 25 percent withhold for shared savings amounts.</p> <p>ACOs participating in Track Two still must have a CMS-approved repayment mechanism.⁸</p>	<p>The elimination of the 25 percent withhold is one example of a number of steps CMS took in the Final Rule to incentivize entities to participate in the MSSP and to increase funds available during the initial portion of the three-year agreement.</p>	
c. <i>Quality Performance Measurement and Scoring</i>	Page 34	<p>As in the one-sided model, the number of quality measurements has been decreased from 65 to 33.</p> <p>The number of quality measure domains has been decreased from five to four, so each domain is now worth 15 percent for a 60 percent maximum sharing rate.⁹</p>		
d. <i>Shared Savings Methodology</i>	Page 35			
i. MINIMUM SAVINGS RATE	Page 35			
ii. ADDITIONAL SHARED SAVINGS PAYMENTS FOR FEDERALLY QUALIFIED HEALTH CENTERS AND RURAL HEALTH CENTERS	Page 35	<p>These incentives are eliminated because FQHCs and RHCs can operate as ACOs under the Final Rule.</p> <p>The elimination of these incentives results in a maximum sharing rate of 60 percent, as opposed to 65 percent under the Proposed Rule.¹⁰</p>	<p>CMS largely tried to make the Final Rule provide greater potential monetary rewards for participating ACOs, but this is one amendment to the Proposed Rule that has the effect of lowering the financial upside for participation. Other available benefits (e.g., FQHC and RHC participation and beneficiary assignment) may compensate for this loss in</p>	

⁸ 42 C.F.R. § 425.204(f)(1)(i).

⁹ 42 C.F.R. § 425.502(d)(1).

¹⁰ 42 C.F.R. § 425.606(d).

	White Paper Cross-Reference	Changes from Proposed Regulations	McDermott Commentary	Action Items
iii. NET SHARING RATE	Page 35		potential shared savings. Since the incentives for FQHC and RHC participation were designed to make a place for these entities in the MSSP, and not necessarily to raise more money for ACOs, it is not surprising that this incentive was eliminated now that FQHCs and RHCs can fully participate as ACOs.	
iv. CALCULATING SHARED LOSSES	Page 35	The smallest percentage of losses for which an ACO can be responsible, or its shared loss rate, is 40 percent. An ACO is required to meet each of the four quality domains in order to achieve the 40 percent shared loss rate. CMS set a shared loss rate maximum of 60 percent, whereas an ACO was potentially responsible for up to 100 percent of losses under the Proposed Rule.	Under the Proposed Rule, achieving the quality metrics was especially important in the two-sided model given the potential for 100 percent ACO responsibility for losses in the event none of the domains was achieved. This potential “stick” has been somewhat diminished, but ACOs can still decrease their shared loss rate by 20 percent by achieving a maximum quality score.	
v. MAXIMUM SHARED SAVINGS AND SHARED LOSS CAP	Page 35	The maximum shared savings is increased to 15 percent of the benchmark amount in each performance year from 10 percent in the Proposed Rule. ¹¹		
e. <i>Ensuring ACO Repayment of Shared Losses</i>	Page 36	Losses will not be carried forward to subsequent performance years to the extent an ACO’s repayment mechanism does not allow CMS to	In addition to the risk of shared losses, the requirement to have a repayment mechanism for shared losses is a significant	

¹¹ 42 C.F.R. Rule § 425.606(e)(2).

	<i>White Paper</i> Cross-Reference	Changes from Proposed Regulations	McDermott Commentary	Action Items
		<p>fully recoup the shared losses for a given performance year.</p> <p>The requirement for a repayment mechanism now only applies to ACOs selecting Track Two unless an ACO choosing Track One requests interim payments during the first performance year.¹²</p> <p>Payment of shared losses must now be made within 90 days of receiving notification from CMS of the shared losses, compared to 30 days in the Proposed Rule.¹³</p>	burden associated with choosing Track Two and is something ACOs choosing Track One can avoid if they forgo interim payments during the first performance year.	
<p>f. <i>Future Participation of Under-Performing Organizations</i></p> <p>g. <i>Public Reporting</i></p> <p>h. <i>Impact on States</i></p>	Page 36	<p>CMS eliminated the requirement prohibiting ACOs that experience a net loss over the term of the initial agreement from future participation in the MSSP.</p> <p>ACOs that experience a net loss during the initial agreement period must describe the cause for the net loss in the application for the subsequent agreement and specify what safeguards are in place to potentially achieve savings under the next agreement.¹⁴</p>		
4. VERIFICATION OF SAVINGS AND LOSSES	Page 37	ACOs will no longer be required to submit a written request for	Since the ACO is still required to make an annual certification	Participating ACOs may want to consider requiring entities

¹² 42 C.F.R. § 425.204(f)(1)(i).

¹³ 42 C.F.R. § 425.606(h).

¹⁴ 42 C.F.R. § 425.600(c).

	<i>White Paper Cross-Reference</i>	Changes from Proposed Regulations	McDermott Commentary	Action Items
		<p>payment with a certification of compliance with program requirements. CMS will notify the ACO of the amount of any savings or losses.¹⁵</p> <p>Although the certification is no longer tied to an ACO's request for payment of shared savings or losses, the ACO must provide a certification whenever data or other information is submitted, and also annually.¹⁶</p>	<p>under the Final Rule regarding data and information submitted by ACO providers/suppliers and individuals or entities performing functions on behalf of the ACO, ACOs should take steps to ensure the data and information submitted by these entities is accurate.</p>	<p>submitting or generating data or information to provide the ACO with a separate certification concerning the accuracy, completeness and truthfulness of their data.</p>
<p>5. DETERMINING FIRST-YEAR PERFORMANCE FOR ACOS BEGINNING APRIL 1 OR JULY 1, 2012</p>		<p>The Final Rule features a mid-year start date for ACOs starting in 2012, so CMS has decided to make the first performance year stretch from an ACO's start date until December 31, 2013. ACOs may choose to start on either April 1 or July 1, 2012, so that there will be either a 21- or 18-month initial performance year for ACOs starting in 2012.</p> <p>An ACO participating in Track One or Track Two has the option to receive an interim payment based on the ACO's first 12 months of performance. This allows an ACO to receive shared savings without completing the entire 21- or 18-month initial performance year. ACOs choosing to receive an</p>	<p>For ACOs choosing not to apply for an interim payment during the first performance year, their first opportunity to receive any shared savings will be well into 2014, since there is a three-month claims run out in calculating an ACO's per capita expenditures, and CMS has not specified a time limit for calculating shared savings. Given the significant up-front expenses in establishing the ACO, the interim payment option may be attractive for many ACOs, especially ACOs in Track Two that already are required to have an adequate repayment mechanism.</p>	<p>ACOs participating in Track One must determine whether the benefits of securing an interim payment during the first performance year outweigh the burden of establishing an adequate repayment mechanism.</p> <p>All ACOs starting in 2012, in either Track One or Track Two, must indicate in their application whether they would like to receive an interim payment during the initial performance year.¹⁹</p>

¹⁵ 42 C.F.R. § 425.606(h).

¹⁶ 42 C.F.R. § 425.302(a)(2), (3).

¹⁷ 42 C.F.R. § 425.204(f)(i).

¹⁸ 42 C.F.R. § 425.608(c).

¹⁹ 42 C.F.R. § 425.204(e)(2)(ii).

	<i>White Paper</i> Cross-Reference	Changes from Proposed Regulations	McDermott Commentary	Action Items
		<p>interim payment are required to have a repayment mechanism in place that is equivalent to the repayment mechanism required of all Track Two ACOs.¹⁷</p> <p>The interim payment represents an ACO's shared savings or shared losses for the initial 12 months and is in addition to the FFS payments all ACOs will receive during their participation. An ACO's quality performance will be determined based on CY 2012 GPRO data. The methodology for determining shared savings or shared losses will be the same for this 12-month period as for other performance years in Track One and Two. Depending on its performance, the ACO may receive an interim shared savings or loss payment.</p> <p>For ACOs starting April 1 or July 1, 2012, the reconciliation for the first performance year will take into account the full 21- or 18-month period. The methodology for determining the ACO's first year performance is adjusted to account for the six or nine months included in CY 2012. This includes adjustments to beneficiary assignment, aggregate expenditure calculation, risk score calculations for assigned beneficiaries, and the methodology for determining the updated benchmark.¹⁸ The savings percentage for the first performance year is calculated by comparing the summed expenditures to the updated benchmark dollars as</p>		

	<i>White Paper</i> Cross-Reference	Changes from Proposed Regulations	McDermott Commentary	Action Items
		<p>determined by the revised methodology. This savings percentage is then compared to the minimum savings rate or minimum loss rate to determine whether the ACO is responsible for any shared savings or losses. As with other performance years, the ACO's shared savings or loss rate will depend on its quality score. Finally, the reconciled amount of shared savings or losses owed for the initial performance year will be net of any interim payments of shared savings or losses.</p>		

	White Paper Cross-Reference	Changes from Proposed Regulations	McDermott Commentary	Action Items
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Section II – G. MONITORING AND TERMINATION

1. MONITORING	Pages 38–39	<p>The provisions related to monitoring ACOs were finalized with minor changes to verbiage and changes to the definition of at-risk beneficiary, and certain provisions previously included under the monitoring provision are now dispersed over several sections of the Final Rule.</p> <p>The Final Rule no longer specifically delineates the five areas of monitoring under the monitoring section: (1) avoidance of at-risk beneficiaries, (2) compliance with quality performance, (3) meeting of eligibility requirements, (4) notification of beneficiaries of participation in an ACO and ability to opt-out of data sharing, and (5) marketing materials and activities.²⁰</p> <p>CMS updated the definition of at-risk beneficiaries by including two additional categories: (1) individuals entitled to Medicare due to disability (note an apparent typo in the preamble and regulatory text refers to individuals entitled to Medicaid due to disability), and (2)</p>	<p>The decision to adopt “file and use” for marketing materials represents a significant improvement over the Proposed Rule, and should reduce some administrative burden associated with obtaining CMS approval of ACO marketing materials.</p> <p>The preamble and regulatory text appear to include an error regarding one of the new categories of at-risk beneficiaries. Although the Final Rule refers to individuals who are entitled to Medicaid due to disability, we believe that CMS intended to refer to individuals who are entitled to Medicare due to disability.</p>	<p>Potential ACOs should review the various operational areas that CMS has identified for monitoring purposes and ensure 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 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 to determine if there is a risk of failure to meet quality performance standards during the performance period.</p>
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²⁰ The Final Rule divides the monitoring section into various provisions. 42 C.F.R. §425.316 delineates monitoring of the avoidance of at-risk beneficiaries and an ACO’s compliance with quality performance metrics. Monitoring related to an ACO meeting eligibility requirements is dispersed throughout various sections of the Final Rule. Monitoring related to notifying beneficiaries of participation in an ACO is finalized at 42 C.F.R. §425.312. Monitoring provisions related to marketing materials and activities is finalized at 42 C.F.R. §425.310.

	<i>White Paper</i> Cross-Reference	Changes from Proposed Regulations	McDermott Commentary	Action Items
		<p>individuals diagnosed with a mental health or substance abuse disorder.²¹ CMS also finalized actions it can take if it concludes an ACO has been avoiding at-risk beneficiaries.²²</p> <p>CMS now allows ACOs to use marketing materials or conduct marketing activities within five days following submission to CMS if the ACO certifies compliance with marketing guidelines.</p> <p>The ACO provision regarding notification to beneficiaries of participation in an ACO and a beneficiary’s ability to opt out of data sharing must conform to the updated marketing guidelines.</p>		
2. CORRECTIVE ACTION PLANS	Pages 39–40	The provisions related to corrective action plans were finalized with minor changes to verbiage. These provisions are also now dispersed over two sections of the Final Rule.		Potential ACOs should review the list of actions that could result in an ACO becoming subject to a CAP (<i>i.e.</i> , those actions that could result in termination of an ACO agreement and incur large losses to the Medicare program) and institute policies and procedures to reduce the potential that a CAP would be necessary.

²¹ See 42 C.F.R. §425.20.

²² *Id.* at §425.316.

	<i>White Paper Cross-Reference</i>	Changes from Proposed Regulations	McDermott Commentary	Action Items
3. TERMINATION	Page 40	<p>ACO provisions related to termination were finalized with minor changes and clarifications.</p> <p>CMS may take pre-termination actions to terminate an ACO from the MSSP, if warranted. The Final Rule allows flexibility for an ACO to specify its preferred method for repaying potential losses and eliminates the 25 percent of FFS-based shared savings payments withhold and related provisions due to early termination from the program.</p> <p>CMS can immediately terminate a participation agreement without pursuing any of the pre-termination actions.</p> <p>The Final Rule clarifies that if the number of beneficiaries assigned to an ACO falls below 5,000 in a given performance year, CMS will issue a warning and place the ACO on a corrective action plan, as opposed to immediately terminating the participation agreement. The ACO will remain eligible for shared savings for the performance year in which CMS issued the warning. If the ACO's assigned population does not return to 5,000 in the end of the next performance year, the ACO is not eligible to share in savings for that performance year.</p>	<p>In the Proposed Rule, CMS proposed that if an agreement was terminated, whether voluntarily or involuntarily, any withhold payments associated with that agreement would be forfeited. Because the Final Rule eliminates the 25 percent withhold, the associated provisions related to forfeiture of the withhold in the event of termination have also been eliminated. This is a welcome change as it reduces some risk associated with participation in the MSSP by removing the withhold forfeiture penalty in the event of termination.</p> <p>CMS will notify an ACO in writing of its termination decision, but does not have a required number of days to provide notice. An ACO must provide CMS with 60 days' prior written notice to terminate its participation agreement.</p>	<p>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.</p> <p>ACOs in rural areas will likely have to align with regional hospitals to ensure that the number of beneficiaries does not fall below 5,000 in a given performance year. ACOs in rural areas should evaluate the risk of termination for failing to meet minimum beneficiaries.</p>

	<i>White Paper</i> Cross-Reference	Changes from Proposed Regulations	McDermott Commentary	Action Items
4. RECONSIDERATION REVIEW PROCESS	Page 41	Provisions related to the reconsideration review process were finalized in various sections of the Final Rule with one primary change: the Final Rule deletes the provision stating that if a reviewing antitrust agency is likely to challenge or recommend challenging the ACO, the ACO is not entitled to reconsideration, appeal, or administrative or judicial review. ²³		
5. AUDITS AND RECORD RETENTION	Page 41	<p>The audits and record retention rule was finalized with minor changes in verbiage and the addition of one new provision.²⁴</p> <p>One example of the minor changes in verbiage is as follows: "... and contracted entities performing functions on behalf of the ACO" changed to "and other individuals or entities performing functions or services related to ACO activities"</p> <p>The Final Rule added a new provision outlining CMS's right to reopen an initial determination and issue a revised initial determination if, as a result of any inspection, evaluation or audit, CMS determined that the amount of shared savings due to the ACO or the amount of shared losses owed by the ACO had been erroneously calculated.</p>		ACO participants must ensure that all agreements with other entities and individuals include the appropriate record retention and audit accessibility provisions.

²³ See 42 C.F.R. §425.800.

²⁴ The provisions related to this section can be found at 42 C.F.R. §425.314.

	<i>White Paper</i> Cross-Reference	Changes from Proposed Regulations	McDermott Commentary	Action Items
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Section II – H. COORDINATION AND OTHER AGENCIES

<p>1. WAIVERS OF CMP, ANTI-KICKBACK AND PHYSICIAN SELF-REFERRAL LAWS</p>	<p>Page 42</p>	<p>A joint CMS and OIG interim Final Rule with comment period (the Final ACO Waivers Rule) was published in the Federal Register concurrently with the Final Rule.</p>	<p>The Final ACO Waivers Rule sets forth the scope, terms and conditions of waivers of four federal laws that would otherwise prohibit or impede the development and operation of ACOs wishing to participate in the MSSP. The four federal laws addressed by the Final ACO Waivers Rule are the federal physician self-referral or Stark Law, the federal anti-kickback statute, the provisions of the CMP law prohibiting hospital payments to a physician to induce the physician to reduce or limit care to a Medicare or Medicaid beneficiary under the physician’s direct care, and the provisions of the CMP law prohibiting inducements to a Medicare or Medicaid beneficiary likely to influence the beneficiary’s choice of a provider, practitioner or supplier (collectively, the F&A Laws). The Final ACO Waivers Rule represents a dramatic departure for CMS and the OIG, especially with regard to enforcement of the Stark Law and the CMP law’s broad restrictions on “gainsharing.” By allowing compensation to physicians to incentivize more efficient and effective care, and by focusing</p>	<p>For a more detailed discussion of the Final ACO Waivers Rule, see McDermott <i>White Paper</i> “ACOs Get Broad Waivers from the Fraud & Abuse Laws,” available at www.mwe.com/info/news/wp1111a.pdf.</p>
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	<i>White Paper</i> Cross-Reference	Changes from Proposed Regulations	McDermott Commentary	Action Items
			on procedural requirements such as (1) determinations by the ACO's governing body that the financial arrangement is reasonably related to the purposes of the MSSP, (2) contemporaneous documentation (but no signed writing requirement), and (3) public disclosure of the arrangement (but not disclosure of the financial details), CMS and the OIG are relieving ACOs and their participants of substantial regulatory uncertainty and burdens that would otherwise interfere with effective participation in the MSSP.	
2. IRS GUIDANCE RELATING TO TAX-EXEMPT ORGANIZATIONS	Page 42	CMS noted that it received some comments related to the tax treatment of ACOs, but tax issues are within the jurisdiction of the IRS, not CMS. Accordingly, these comments were shared with the IRS.		
3. ANTITRUST POLICY STATEMENT	Page 42	The Antitrust Agencies released concurrently with the Final Rule a final Antitrust Policy Statement in response to the comments received on the proposed Antitrust Policy Statement.	The Antitrust Policy Statement provides that the Agencies will apply rule of reason (not per se) analysis to an ACO's joint contracting activities with commercial payors, as long as the ACO meets CMS's requirements for participation—and participates—in the MSSP, and uses the same governance structures and clinical processes to serve patients in Medicare and commercial	For a more detailed discussion of the Antitrust Policy Statement, see McDermott <i>On the Subject</i> "FTC/DOJ Remove Mandatory Antitrust Review for MSSP-Participating ACOs in Final Policy Statement," available at http://www.mwe.com/index.cfm/fuseaction/publications.nldetail/object_id/bce4293d-3342-48dd-8cab-4a1f4f8f8583.cfm .

	<i>White Paper</i> Cross-Reference	Changes from Proposed Regulations	McDermott Commentary	Action Items
			markets. The Antitrust Policy Statement also creates a safety zone providing that the Agencies will not challenge, absent extraordinary circumstances, an ACO comprising independent ACO participants providing a common service that possess a combined share of 30 percent or less of each common service in each participant's primary service area.	For further guidance on antitrust enforcement policy, review the final Antitrust Policy Statement.
4. PROHIBITION AGAINST THE SHARED SAVINGS PROGRAM PARTICIPATION BY ACOS WITH MARKET POWER	Page 43			
a. <i>Coordinating the Shared Savings Program Application with the Antitrust Agencies</i>	Page 43	<p>CMS adopts a three-pronged approach to maintain competition among ACOs:</p> <p>The Antitrust Agencies will offer a voluntary expedited antitrust review to any newly formed ACO before it is approved to participate in the MSSP.</p> <p>CMS will share with the Antitrust Agencies aggregate claims data regarding allowable charges and fee-for-service payments as well as a copy of the application for all ACOs formed after March 23, 2010.²⁵</p>	CMS is moving away from its initial proposal to require mandatory antitrust review and the submission of a letter from an Antitrust Agency confirming that it has no intent to challenge certain ACOs formed after March 23, 2010. Eligibility to participate in the MSSP will not be conditioned upon whether an ACO has obtained a letter from the Antitrust Agencies. An ACO will be accepted into the MSSP regardless of whether it voluntarily obtains a letter from the Antitrust Agencies and regardless of the contents of any letter it may have voluntarily	

²⁵ 42 C.F.R. § 425.202.

	<i>White Paper</i> Cross-Reference	Changes from Proposed Regulations	McDermott Commentary	Action Items
b. <i>Competition and Quality of Care</i>	Page 43	<p>The Antitrust Agencies will rely on their existing enforcement processes for evaluating concerns raised about an ACO's formation or conduct and filing antitrust complaints when appropriate.</p> <p>CMS also requested that the Antitrust Agencies conduct a study examining how ACOs participating in the MSSP affect the quality and price of health care in private markets. CMS will use the results of this study to evaluate whether it should expand its eligibility criteria to consider competition concerns more explicitly.</p>	obtained from the Antitrust Agencies, assuming that the ACO meets the other MSSP eligibility requirements.	
c. <i>Competition, Price and Access to Care</i>	Page 43			