April 19, 2011

Diving into the Federal Issuances Implementing the Medicare Shared Savings Program: A Summary of Topic Areas On Which Government Agencies Specifically Requested Public Comments

Resource Links

CMS – Proposed Regulations
http://edocket.access.gpo.gov/2011/pdf/2011-7880.pdf

OIG/CMS – Notice with Comment
http://edocket.access.gpo.gov/2011/pdf/2011-7884.pdf

FTC/DOJ – Proposed Statement of Antitrust Enforcement Policy
http://www.ftc.gov/opp/aco

IRS – Notice Requesting Comments
http://www.irs.gov/pub/irs-drop/n-11-20.pdf

Important Dates

March 23, 2010
Affordable Care Act signed into law
May 31, 2011
Comments due to FTC/DOJ and IRS
June 6, 2011
Comments due to CMS and OIG
January 1, 2012
Affordable Care Act requires the Medicare Shared Savings Program to be established

On March 31, 2011, the Centers for Medicare & Medicaid Services ("**CMS**") released a notice of proposed rulemaking ("**NPRM**") for the Medicare Shared Savings Program ("**MSSP**"), pursuant to Section 3022 of the Affordable Care Act ("**ACA**"). The proposed regulations establish requirements for the creation of accountable care organizations ("**ACOs**") eligible for participation in the voluntary MSSP. At the same time, the Department of Health and Human Services' Office of the Inspector General ("**OIG**") and CMS released a Notice with Comment Period to solicit comments regarding proposed waivers from the federal health care program fraud and abuse laws.

Also on March 31, 2011, the Federal Trade Commission ("**FTC**") and the Department of Justice ("**DOJ**") issued a Notice with Comment Period soliciting comments regarding proposed antitrust enforcement policies, and the Internal Revenue Service ("**IRS**") issued Notice 2011-22, outlining proposed guidance for tax-exempt organizations participating in the MSSP.

Each of these four separate issuances gives the public an opportunity to provide the government agencies with comments. Set forth below is a listing of each of the places in which the government agencies specifically requested comments from the public. ***Comments to CMS and OIG are due on June 6, 2011, and comments to the FTC, DOJ, and IRS are due on May 31, 2011***.

Even those organizations that may ultimately decide not to participate in the MSSP should still take advantage of this unique opportunity to provide these agencies with comments and help shape the modifications being proposed to the Medicare program.

CMS Notice of Proposed Rulemaking

CMS has requested public comment on its proposed requirements for creating and implementing the MSSP[1]. Public comments are due by 5:00 p.m. on June 6, 2011. General comments about all aspects of the program are invited. In addition, the following table summarizes the specific topic areas on which CMS has requested comments.

1 See 76 Fed. Reg. 19,528 (Apr. 7, 2011).

Citation	Section	Comments Are Requested Concerning:
76 Fed. Reg. 19,539	SECTION II.B.1. Eligible Entities	The types of providers that should be included or excluded from participation in an ACO
76 Fed. Reg. 19,540-19,541	SECTION II.B.2.a. Legal Entity	Whether ACOs should be distinct legal entities The proposed legal structure requirements for ACOs
76 Fed. Reg. 19,541	SECTION II.B.2.b. Governance	Whether allowing existing entities to be ACOs would complicate efforts by CMS to monitor and audit ACOs Whether CMS should require ACOs to be separate legal entities
76 Fed. Reg. 19,541	SECTION II.B.2.c. Composition of the Governing Body	The composition of the ACO governing board
76 Fed. Reg. 19,543-19,544	SECTION II.B.3. Leadership and Management Structure	Documents ACOs would be required to submit to show compliance with various ACO requirements Alternative methods that could be used to verify compliance with ACO requirements The proposed requirements relating to the ACO leadership and management structure, and whether these requirements would discourage participation in the MSSP
76 Fed. Reg. 19,544	SECTION II.B.5. Agreement Requirement	Whether ACO participation should be limited to a three-year period Whether CMS should require ACOs to provide a copy of the ACO agreement to participants, providers, and suppliers The process for extending certain obligations of the ACO to ACO participants
76 Fed. Reg. 19,544	SECTION II.B.6. Distribution of Savings	Whether CMS should make shared savings payments directly to the ACO Whether shared savings payments should be made to ACOs that are non-Medicare-enrolled entities
76 Fed. Reg. 19,545	SECTION II.B.7. Sufficient Number of Primary Care Providers and Beneficiaries	The proposed requirement that an ACO have more than 5,000 beneficiaries historically assigned to it each year over the three-year benchmarking period The proposal giving CMS authority to monitor an ACO through a corrective action plan or terminate an ACO agreement if the ACO is no longer meeting eligibility requirements
76 Fed. Reg. 19,546	SECTION II.B.8. Required Reporting on Participating ACO Professionals	Whether more prescriptive criteria may be appropriate for meeting the requirements under Sec.1899(b)(2)(G) of the ACA, which requires an ACO to define processes that promote evidence-based medicine and patient engagement, report quality and cost measures, and coordinate care Whether CMS should simply require documentation of an ACO's plan to comply with Sec. 1899(b)(2)(G) or identify specific criteria that ACOs would have to meet in order to comply
76 Fed. Reg. 19,547	SECTION II.B.9.d. Processes To Promote Coordination of Care	Whether the joint CMS/OIG notice adequately addresses the fraud and abuse risks that can arise when an ACO provides free services

Citation	Section	Comments Are Requested Concerning:
76 Fed. Reg. 19,549	SECTION II.B.10. Patient-Centeredness Criteria	Whether the proposed list of patient-centeredness criteria should be narrowed Whether the proposed patient-centeredness criteria will sufficiently ensure that ACOs are patient centered Whether the patient-centeredness criteria will discourage participation in the MSSP
76 Fed. Reg. 19,549	SECTION II.B.10.a. Beneficiary Experience of Care Survey	Appropriate survey tools for ACO quality assessment
76 Fed. Reg. 19,549	SECTION II.B.10.b. Patient Involvement in Governance	Whether Medicare beneficiaries should serve on ACO governing bodies Whether there should be minimum standards for beneficiary participation on ACO governing bodies Whether the Medicare beneficiary advisory panel or committee should encourage patients to participate in ACO governance Whether requiring ACOs to partner with Medicare beneficiaries would discourage participation among smaller entities
76 Fed. Reg. 19,550	SECTION II.B.10.c. Evaluation of Population Health Needs and Consideration of Diversity	The proposal that ACOs have a process for evaluating the health needs of the population
76 Fed. Reg. 19,550	SECTION II.B.10.d. Implementation of Individualized Care Plans and Integration of Community Resources	The proposal that ACOs use individualized care plans for targeted populations The proposal that ACOs describe how they will partner with community stakeholders
76 Fed. Reg. 19,552	SECTION II.B.12.b. Compliance with Program Requirements	Whether the ACO should have ultimate responsibility for compliance with all terms and conditions of its agreement with CMS The proposal that all contracts or arrangements between an ACO and entities performing ACO activities, such as ACO participants, require compliance with the obligations under the ACO's three-year agreement
76 Fed. Reg. 19,552	SECTION II.B.12.c. Conflicts of Interest	The proposal that ACOs have a procedure for determining whether a conflict of interest exists and set forth a process to address any conflicts that arise
76 Fed. Reg. 19,552	SECTION II.B.12.d. Screening of ACO Applicants	ACO program integrity screening results that would justify rejection of an application or increased scrutiny
76 Fed. Reg. 19,553	SECTION II.C.1. Options for Start Date of the Performance Year	Alternatives to a January 1 start date that would encourage participation in the MSSP
76 Fed. Reg. 19,554	SECTION II.C.2. Timing and Process for Evaluating Shared Savings	Worries that high-cost claims may be filed after the claims run-out period, affecting the accuracy of the amount of the shared savings payment Considerations that might make a three-month claims run-out period more appropriate than the proposed six-month claims run-out period

Citation	Section	Comments Are Requested Concerning:
76 Fed. Reg. 19,555	SECTION II.C.4. Sharing Aggregate Data	Proposals relating to the sharing of aggregated data on the beneficiary use of health care services Types of data that would help ACOs coordinate care, improve health, and produce efficiencies
76 Fed. Reg. 19,556	SECTION II.C.5. Identification of Historically Assigned Beneficiaries	Providing ACOs with a list of beneficiary names, date of birth, sex, and a Health Insurance Claim Number derived from the assignment algorithm used to generate the three-year benchmark
76 Fed. Reg. 19,557	SECTION II.C.6. Sharing Beneficiary-Identifiable Claims Data	The proposal that each ACO explain how it will use data to assess quality; evaluate the performance of ACO participants, providers, and suppliers; and improve the health of its assigned beneficiary population Proposed requirements regarding data use agreements
76 Fed. Reg. 19,560	SECTION II.C.6.a.(2).a Beneficiary Opportunity To Opt-Out of Claims Data Sharing	The proposal to share both aggregate and beneficiary identifiable data with ACOs The implications for sharing protected health information with ACOs, and the use of a beneficiary opt-out, as opposed to an opt-in, to obtain beneficiary consent to the sharing of his or her information
76 Fed. Reg. 19,561	SECTION II.C.8. Managing Significant Changes to the ACO During the Agreement Period	The proposal that an ACO may not add ACO participants during the course of the three-year agreement, and its impact on small or rural ACOs Notification requirements triggered by: • Changes in an ACO's composition of participants, providers, and suppliers • Deviation from the information provided by the ACO in its approved application Changes that may make the ACO unable to complete its three-year agreement
76 Fed. Reg. 19,562	SECTION II.C.9. Future Participation of Previously Terminated Program Participants	Whether requirements for denying participation to ACOs that under-perform would discourage the formation of ACOs
76 Fed. Reg. 19,564	SECTION II.D.1. Operational Identification of an ACO	The proposal to require reporting of tax identification numbers along with information about the national provider identifiers associated with the ACO
76 Fed. Reg. 19,565	SECTION II.D.2. Definition of Primary Care Services	The proposal to assign beneficiaries to the primary care providers who are providing services to the beneficiaries Options that may better address the delivery of primary care services by specialists The definition of "primary care services"
76 Fed. Reg. 19,566	SECTION II.D.3. Prospective vs. Retrospective Beneficiary Assignment To Calculate Eligibility for Shared Savings	The combined approach of retrospective beneficiary assignment for purposes of determining eligibility for shared savings balanced by the provision of beneficiary data (names, date of birth, etc.) and aggregate beneficiary level data for the assigned population of Medicare beneficiaries during the benchmark period Alternate assignment approaches, including the prospective method of assignment

Citation	Section	Comments Are Requested Concerning:
76 Fed. Reg. 19,567	SECTION II.D.4. Majority vs. Plurality Rule for Beneficiary Assignment	The proposal to assign patients based upon a plurality rule Whether there should be a minimum threshold number of primary care services that a beneficiary should receive from physicians in the ACO in order to be assigned to the ACO under the plurality rule and, if so, where that minimum threshold should be set
76 Fed. Reg. 19,568	SECTION II.D.5. Beneficiary Information and Notification	The requirement that an ACO provide beneficiaries with notice of participation in, or termination from, the MSSP Other notifications, including: • Informing consumers about objectives of the MSSP that might have the most impact on the beneficiary • Communication to beneficiaries about matters that will not change under the MSSP The appropriate form and content of beneficiary notification requirements
76 Fed. Reg. 19,592	SECTION II.E.2.c. Proposed Quality Measures for Use in Establishing Quality Performance Standards that ACOs Must Meet for Shared Savings	Measures that should be included in, or excluded from, the calculation of the ACO Quality Performance Standard • Implications of including or excluding any such measures • Potential variations or substitutions to the proposed measures The potential narrowing of the proposed measures for scoring purposes The process for retiring or adjusting the weights of domains, modules, or measures over time
76 Fed. Reg. 19,592	SECTION II.E.3.a. Requirements for Quality Measures Data Submission by ACOs; General	The proposed data submission requirements Whether alternative data submission methods should be required or considered
76 Fed. Reg. 19,593	SECTION II.E.3.b. GPRO Tool	Administrative burdens associated with reporting quality data
76 Fed. Reg. 19,593	SECTION II.E.4.a. Quality Performance Standards; General	The two alternative options for establishing quality standards: • "Rewards for better performance" approach • "Minimum quality threshold" approach
76 Fed. Reg. 19,597	SECTION II.E.4.c.(1) Minimum Quality Threshold	Under the minimum quality threshold approach, the pros and cons of establishing eligibility for shared savings based on achieving performance on the quality measures at the 50th percentile as the minimum quality threshold

Citation	Section	Comments Are Requested Concerning:
76 Fed. Reg. 19,597	SECTION II.E.c.(2) Considerations in Establishing a Quality Threshold	Under the performance scoring option and the quality threshold option: • The appropriateness of weighting all domains equally in determining an ACO's quality performance • Whether certain domains and/or specific measures should be weighted more heavily • Alternatives that would blend these two approaches Whether to set the quality performance standard of the first program year at the reporting level and to raise the standard to reflect performance in subsequent years Proposed quality measures scoring methodologies under the one-sided and two-sided risk models Requiring ACOs to report on all 65 quality measures versus requiring ACOs to report on only a subset of the measures based on their level of readiness for the MSSP
76 Fed. Reg. 19,600	SECTION II.E.5. Incorporation of Other Reporting Requirements Related to the Physician Quality Reporting System and Electronic Health Records Technology Under Section 1848 of the Act	Whether a percentage-based requirement predicated on the meaningful use of certified electronic health record ("**EHR**") technology by the second performance year should be specified for hospitals • Whether an exclusion or exemption to such meaningful use standard for hospitals would be necessary where an ACO includes only one eligible hospital or no hospital Incorporating the Physician Quality Reporting System requirements, payments, and certain metrics under the MSSP
76 Fed. Reg. 19,601	SECTION II.E.6. Public Reporting	Public reporting of ACO cost and quality measure data • Whether the proposed list includes elements that should not be required • Whether the proposed list excludes elements that are important for achieving transparency or meaningful public disclosure • Whether the format for providing information to beneficiaries should be standardized Proposed reporting requirements and new reporting requirement recommendations that could be considered for future program years Who should be required to make the reported cost and quality measure data publicly available – the ACOs themselves or CMS?
76 Fed. Reg. 19,602	SECTION II.E.7. Aligning ACO Quality Measures with Other Laws and Regulations	The best and most appropriate way to align quality domains, categories, specific measures, and rewards across federal health care programs Whether quality standards in different ACA programs should use the same definition of domains, categories, specific measures, and rewards for performance across all programs to the greatest extent possible, taking into account meaningful differences in affected parties
76 Fed. Reg. 19,603	SECTION II.F.1. Shared Savings Determination; Background	Options for structuring the MSSP

Citation	Section	Comments Are Requested Concerning:
76 Fed. Reg. 19,604	SECTION II.F.3.a. Establishing an Expenditure Benchmark; Background	Establishing each ACO's benchmark based on: • Parts A & B expenditures of beneficiaries who would have been assigned to the ACO in each of the three years prior to the start of the ACO's agreement period • Parts A & B expenditures of beneficiaries who are actually assigned to the ACO during each performance year for each of the three years prior to the start of the ACO's agreement period
76 Fed. Reg. 19,605-19,606	SECTION II.F.3.c. Option 2	Adjustment approaches when a beneficiary does not have three full years of "immediately prior" Medicare eligibility for purposes of establishing each ACO's benchmark Methods for adjusting for decedents during the course of the performance year under Option 2
76 Fed. Reg. 19,606	SECTION II.F.3.d. Summary	The merits and limitations of the two options for establishing ACO benchmarks • How each approach might affect the willingness of ACOs or particular types of ACOs to participate in the MSSP • Whether an approach creates incentives for ACOs to seek or avoid certain kinds of beneficiaries • The impact of each approach on Medicare expenditures
76 Fed. Reg. 19,608	SECTION II.F.4. Adjusting the Benchmark and Average Per Capita Expenditures for Beneficiary Characteristics	The proposed risk adjustment model and alternative approaches that should be considered (*i.e.*, using the Medicare Advantage "new enrollee" demographic risk adjustment model or applying a coding intensity cap on annual growth in the risk scores of an ACO's assigned beneficiary population) The proposal to audit ACOs with high levels of risk score growth relative to their peers and to adjust the risk scores used for purposes of establishing the three-year benchmark accordingly
76 Fed. Reg. 19,608	SECTION II.F.5. Technical Adjustments to the Benchmark: Impact of IME and DSH	How including indirect medical education ("**IME**") and disproportionate share hospital ("**DSH**") payments in, or excluding them from, the per capita costs included in the benchmark for an ACO could likely affect access to medically necessary services provided at teaching/DSH hospitals
76 Fed. Reg. 19,609	SECTION II.F.6. Technical Adjustments to the Benchmark: Impact of Geographic Payment Adjustments on the Calculation of the Benchmark	How including geographic payment adjustments in, or excluding them from, the calculation of benchmark expenditures will impact providers, especially in areas that are affected by temporary geographic adjustments
76 Fed. Reg. 19,609	SECTION II.F.7. Technical Adjustments to the Benchmark: Impact of Bonus Payments and Penalties on the Calculation of the Benchmark and Actual Expenditures	The impact of excluding Medicare expenditures or savings for incentive payments and penalties for programs, such as value-based purchasing initiatives and the meaningful use of EHRs, from calculations of the benchmark and expenditures during the agreement period

Citation	Section	Comments Are Requested Concerning:
76 Fed. Reg. 19,610	SECTION II.F.8.a. Flat Dollar vs. Growth Rate as a Benchmark Trending Factor	The options considered for trending forward the per capita costs for each year in order to obtain the benchmark for the first agreement period
76 Fed. Reg. 19,610	SECTION II.F.8.b. National vs. Local Growth Rate as a Benchmark Trending Factor	The proposal to use the national growth rate in Medicare Parts A and B expenditures for fee-for-service beneficiaries for trending forward the fixed benchmark versus using a local growth rate
76 Fed. Reg. 19,610	SECTION II.F.9. Updating the Benchmark During the Agreement Period	The proposal to update the benchmark by the projected absolute amount of growth in national per capital expenditures versus updating the benchmark by the lower of the national projected absolute amount of growth in national per capita expenditures or the local/state-projected absolute amount of growth in per capita expenditures
76 Fed. Reg. 19,613	SECTION II.F.10. Minimum Savings Rate (MSR) and Sharing Rate	The most appropriate means to establish the MSR for an ACO, including the appropriate confidence intervals
76 Fed. Reg. 19,613	SECTION II.F.11. Net Sharing Rate	Options considered for determining the amount of savings that ACOs under the one-sided model could be eligible to receive
76 Fed. Reg. 19,614	SECTION II.F.12. Additional Shared Savings Payments	Alternate options for establishing a payment preference with a sliding scale for ACOs that include federally qualified health centers ("**FQHCs**") or rural health clinics ("**RHCs**") as ACO participants • The appropriate method to measure FQHC/RHC involvement • The appropriate level of incentives for FQHC/RHC involvement Methods to provide a preference to ACOs that serve a large dual-eligible population or that enter and maintain similar arrangements with other payers
76 Fed. Reg. 19,616	SECTION II.F.14. Performance Payment Limit	The proposed payment limits of 7.5 percent of an ACO's benchmark for the first two years of the agreement under the one-sided model and 10 percent for the two-sided model Whether a higher limit would be more appropriate Whether differential limits should be established based on an ACO's readiness, including the criteria that would be applied, the methods used to assess readiness, and how differential limits should be structured
76 Fed. Reg. 19,618	SECTION II.G.2. Two Tracks Provide Incremental Approach to Incorporating Risk	The proposal to require ACOs that enter the program on Track 1 to migrate to the two-sided model Other options for incorporating a two-sided model into the MSSP, including mechanisms for transitioning ACOs to two-sided risk arrangements
76 Fed. Reg. 1,9619	SECTION II.G.3.a. Beneficiary Notification and Protections	The sufficiency of proposed monitoring procedures to guard against ACOs trying to avoid at-risk beneficiaries • Additional areas and mechanisms for monitoring two-sided model ACOs

Citation	Section	Comments Are Requested Concerning:
76 Fed. Reg. 19,620	SECTION II.G.3.b. Eligibility Requirements	Whether additional eligibility requirements are necessary for ensuring that ACOs entering the two-sided model would be capable of repaying CMS if actual expenditures exceed their benchmark
76 Fed. Reg. 19,620	SECTION II.G.3.c. Quality Performance Measurement and Scoring	Alternative approaches for incorporating features that mirror the quality performance standard proposed for the one-sided model into determining the shared savings and shared losses under the two-sided model
76 Fed. Reg. 19,623	SECTION II.G.3.e. Ensuring ACO Repayment of Shared Losses	Options for ensuring that an ACO maintains an adequate repayment mechanism through monitoring activities and an appropriate amount of funds to repay potential losses Options for ensuring repayment if an ACO's repayment mechanism does not enable CMS to fully recoup the losses for a given performance year
76 Fed. Reg. 19,623	SECTION II.G.3.f. Future Participation of Under-Performing Organizations	The proposal to deny continued participation in the MSSP for ACOs that under-perform
76 Fed. Reg. 19,623	SECTION II.G.3.g. Public Reporting	The proposal to require the same public reporting under the one-sided and two-sided models, including reporting on the amount of losses for an ACO under the two-sided model Whether there is any additional information that two-sided model ACOs should publicly report
76 Fed. Reg. 19,623	SECTION II.G.3.h. Impact on States	Whether any of the proposals for the two-sided model in particular, or the MSSP in general, would trigger the application of any state insurance laws Ways that CMS can work with ACOs and states to minimize the burden of any additional regulation
76 Fed. Reg. 19,624	SECTION II.H. Monitoring and Termination of ACOs	Actions that may be appropriate for CMS to take prior to terminating an ACO from the MSSP
76 Fed. Reg. 19,625	SECTION II.H.1. Monitoring Avoidances of At Risk Beneficiaries	The proposed definition of "at-risk beneficiary" Whether other beneficiary characteristics should be considered in determining if a beneficiary is "at-risk" Whether lesser sanctions may be appropriate when an ACO avoids at-risk beneficiaries, such as the cessation of, or a reduction in, the assignment of new beneficiaries to the ACO; a reduction in the amount of the shared savings payment; or a fine for each instance of at-risk beneficiary avoidance
76 Fed. Reg. 19,627	SECTION II.H.3. Terminating an ACO Agreement	The proposed termination of an ACO's agreement for failure of the ACO to submit, obtain approval for, or implement a corrective action plan, or for failure of the ACO to demonstrate improved performance upon completion of the corrective action plan, resulting in termination Additional conditions that could merit the termination of an ACO agreement

Citation	Section	Comments Are Requested Concerning:
76 Fed. Reg. 19,628	SECTION II.H.4. Reconsideration Review Process	The structures and procedure of an appropriate review process for ACOs terminated for avoidance of at-risk beneficiaries or other reasons not exempted from review by statute
76 Fed. Reg. 19,628	SECTION II.I.1. Waivers of CMP, Anti Kickback, and Physician Self Referral Laws	The proposed waivers applicable to the MSSP developed by CMS and OIG
76 Fed. Reg. 19,628	SECTION II.I.2. IRS Guidance Relating to Tax Exempt Organization	Whether existing guidance relating 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 What guidance is necessary for tax-exempt organizations participating in ACOs that conduct activities unrelated to the MSSP
76 Fed. Reg. 19,633	SECTION V.B. Statement of Need	The assumptions and analysis presented in the regulatory impact section presenting the costs and benefits of the proposed rule
76 Fed. Reg. 19,638	SECTION V.C.3 Impact on Providers and Suppliers	The costs and benefits of establishing and maintaining an ACO, including total ACO expenditures for the startup investment and annual operating costs for the three years of the MSSP
76 Fed. Reg. 19,639	SECTION V.D. Alternatives Considered	Other potentially effective and reasonably feasible alternatives to the design of the MSSP, especially those that reduce burdens and maintain flexibility and freedom of choice for the public

CMS/OIG Notice with Comment Period

The CMS/OIG Notice with Comment Period solicits comments regarding the proposed fraud and abuse waivers for participants in the MSSP, whether waivers are necessary for participants in non-MSSP ACO activities, and waivers for demonstrations and pilot programs conducted by the Centers for Medicare and Medicaid Services Center for Innovation ("**CMMI**").[2] ***Comments are due by 5:00 p.m. on June 6, 2011***.

The following table summarizes the specific topic areas on which CMS and OIG have requested comments.

Citation	Section	Comments Are Requested Concerning:
76 Fed. Reg. 19,657	SECTION II: Proposed Waivers	The scope of the proposed waivers under the Physician Self-Referral Law, Anti-Kickback Statute, and the prohibition on hospital payments to physicians to induce or limit services
76 Fed. Reg. 19,659	SECTION III: Additional Waiver Design Considerations	Whether waivers are necessary for remuneration directly related to forming an ACO, implementing the governance and administrative requirements applicable to the ACO under the MSSP, or building technological or administrative capacity needed to achieve the MSSP's cost and quality goals

2 76 Fed. Reg. 19,655 (Apr. 7, 2011).

Citation	Section	Comments Are Requested Concerning:
cont'd., 76 Fed. Reg. 19,659	*cont'd.* SECTION III: Additional Waiver Design Considerations	The exact type of expenses and corresponding financial arrangements that might be covered by a waiver for initial investments or startup expenses, and the period of time during which an investment or payment would be considered an "initial" investment or a "startup" expense Safeguards that could be incorporated to protect patients or federal health care programs from fraud and abuse (*e.g.*, should remuneration in an arrangement that is covered by a waiver be required to be commercially reasonable?) Whether waivers for arrangements between ACO participants (other than those arrangements necessary to distribute shared savings payments) are necessary for, and directly related to, operating a MSSP ACO or achieving the integrated care, cost savings, and quality goals of the MSSP (and, if so, what types of financial arrangements should be covered by the waivers and should such financial arrangements be required to be commercially reasonable and reflect fair market value?) Whether waivers for arrangements between the ACO, its ACO participants, and outside entities or individuals (other than those arrangements necessary to distribute shared savings payments) are necessary for, and directly related to, operating a MSSP ACO or achieving the integrated care, cost savings, and quality goals of the MSSP Whether waivers are necessary to address distributions of shared savings payments received by an ACO from a private payer, the scope and design of such waivers, and whether any specific conditions are needed, or should be imposed, to prevent fraud and abuse Whether there are any financial arrangements not addressed in the CMS/OIG Notice with Comment Period for which waivers should apply; why such waivers would be necessary for, and directly related to, the operations of a MSSP ACO; why no current exception or safe harbor applies to such arrangements; and what conditions, if any, should be applicable to such a waiver The duration of any waiver granted Any additional safeguards that might be necessary to protect patients and the federal health care programs Whether the standard related to which activities under the fraud and abuse laws are waived (*e.g.*, that the activity be "necessary for and directly related to" the ACO's participation in the MSSP) is appropriate, or whether other standards should be employed to ensure that a waiver of the fraud and abuse laws is limited to the MSSP's purposes Whether additional or different waivers may be necessary for ACOs participating in the two-sided risk model Whether the existing exception and safe harbor relating to electronic health record arrangements, currently scheduled to end January 1, 2014, should be extended through the deployment of a waiver Under what circumstances it would be necessary for the Secretary of the Department of Health and Human Services to waive, in whole or in part, the prohibition on inducements offered to Medicare and Medicaid beneficiaries in connection with the MSSP Whether final waivers should be published contemporaneously with, in advance of, or soon after the MSSP final rule is issued

Citation	Section	Comments Are Requested Concerning:
76 Fed. Reg. 19,660	SECTION IV: Center for Medicare and Medicaid Innovation: Solicitation of Public Comments on Waiver Design Considerations	How to best exercise separate waiver authority for CMMI's demonstrations and pilot programs

FTC/DOJ Notice with Comment Period

On March 31, 2011, the FTC and DOJ issued the "Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program" ("**Proposed Statement**").[3] ***Comments are due by May 31, 2011***.

Specifically, the FTC and DOJ have requested comments regarding the following:

- Whether (and why) the guidance in the Proposed Statement should be changed in any respect;
- Whether other sources of data exist that an ACO applicant could utilize to determine its relevant Primary Service Area shares for physician services rarely used by Medicare beneficiaries (*e.g.*, pediatrics, obstetrics, and neonatal care) and inpatient hospital services located in states where all-payer hospital discharge data are not available; and
- Whether providing the documents and information required to obtain an expedited antitrust review will present an undue burden on ACO applicants. [4]

IRS Notice

The IRS issued Notice 2011-20, which solicits comments regarding the need for additional tax guidance for tax-exempt organizations, including tax-exempt hospitals, participating in the MSSP.[5] ***Comments are due by May 31, 2011.***

Specifically, the IRS has requested comments regarding the following:

- Whether additional guidance is needed to facilitate participation by a tax-exempt organization in the MSSP and, if so, what criteria or requirements should be analyzed in determining whether participation by a tax-exempt organization in the MSSP through an ACO is consistent with the tax-exempt entity's status under § 501(c)(3), and whether the tax-exempt organization is receiving unrelated business income;
- Whether guidance is necessary regarding a tax-exempt organization's participation in a non-MSSP ACO, and how a tax-exempt organization's participation in non-MSSP activities further, or are substantially related to, an exempt purpose; and
- What criteria, requirements, and safeguards should be included in guidance to ensure the furtherance of tax-exempt purposes?[6]

3 Proposed Statement of Antitrust Enforcement Policy, available at http://www.ftc.gov/opp/aco.
4 *Id.* at 16.
5 Notice Requesting Comments, available at http://www.irs.gov/pub/irs-drop/n-11-20.pdf.
6 *Id.* at 8-9.

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For more information about this issue of IMPLEMENTING HEALTH AND INSURANCE REFORM, please contact one of the authors below or the member of the firm who normally handles your legal matters.

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Health Employment And Labor Summit – June 7, 2011, National Press Club, Washington, DC

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