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HEALTH LAW REPORTER
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Assessing the Impact of the Medicare Shared Savings Program Proposed Rule on Accountable Care Organization Development: Further Observations at the Nexus of Policy, Business, and Law

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Introduction

As I write this article, we are about a day out from a near government shutdown, a week out from the issuance of the Medicare Shared Savings Program (MSSP) proposed rule,[1] a year out from the passage of the Affordable Care Act (ACA)[2] and 10 years out from the publication of IOM's *Crossing the Quality Chasm*.[3] These events all are linked.

The *Chasm* report, in noting that there is a chasm between the health care we have in the United States and what we could have, defined health care quality as care that is safe, effective, efficient, patient-centered, timely, and equitable. That definition and that vocabulary is the intellectual underpinning for the payment and delivery reform provisions of the ACA and the detailed specifics of the MSSP proposed rule. And the challenge of slowing the unsustainable cost trajectory of health care in America, while also making health care better, safer,

[1] Medicare Shared Savings Program: Accountable Care Organizations, 76 Fed. Reg. 19,528 (proposed April 7, 2011) (to be codified at 42 C.F.R. § 425.5).

[2] Patient Protection and Affordable Care Act, Pub. L. No. 111-148 (2010) (ACA), as amended by The Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152 (HCERA).

[3] *Crossing the Quality Chasm,* Committee on Quality of Health Care in America, Institute of Medicine, 2001.

 ISSN 1064-2137

and more coordinated is a key element—if not *the* key element—of the entire budget debate.

So the proposed rule is important. While there is widespread consensus that accountable care—better coordinated care, more transparent to the consumer, using evidence-based measures to achieve improved patient outcomes, increased patient satisfaction, and greater cost-efficiency—is the direction in which our health care system needs to go, there is uncertainty and disagreement as to whether ACOs in general, and Medicare ACOs in particular, constitute the best way to get there. We know that to achieve more accountable care, both the payment system and delivery system, in both the public and private sectors, will need to change in a reasonably aligned way.

One of the risks to positive movement down the pathway to accountable care is if the MSSP proves to be unsuccessful. While there are many provisions in the ACA that relate to accountable care,[4] most establish demonstration or pilots. But Congress chose to create the MSSP as a permanent program, set to begin Jan. 1, 2012. Section 3022 of the ACA, which the proposed rule implements, was quite specific as to many of the MSSP's requirements.[5] The explosion in the health care industry of interest in ACOs and the buildup of expectations during the long wait for the publication of the proposed rule has been extraordinary. Submissions to the Centers for Medicare & Medicaid Services in advance of the issuance of the proposed rule were voluminous, reflecting the huge interest in this subject among health care providers, purchasers, payers, and consumers across America.

Given the incredible proliferation of policy, business, and legal thinking about ACOs that has taken place since the passage of the ACA, CMS's initial effort to describe a program of payment and delivery reform built around the ACO ''model'' contributes importantly to the national dialogue on accountable care and gives providers a first look at CMS's detailed requirements for the MSSP. The way CMS has further defined ACOs and laid out the requirements to participate in the MSSP will not only ultimately determine the success of the MSSP but also will no doubt affect the shape of burgeoning ACO efforts at the state level for Medicaid programs and in the commercial market.

The CMS Administrator's Perspective

Dr. Donald M. Berwick had the following things to say about ACOs and the MSSP regulations in a speech at the Brookings Institution Feb. 1, 2011. These comments are worth remembering as we assess the proposed rule:

> There will be a comment period that I hope you will all take seriously. But of course you know this issue, as we engage in this expedition toward integrated care. What will risk look like? Shared savings only? Upside/downside? Partial cap, full cap? What would work and for whom? Who can play in each of those different conditions?
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> The proposed rule will be a core model. It will be what anybody can play with. But we all know there are places out there that are ready to surge ahead to a completely different level of integration. They've been there already or are en route. Wouldn't it be nice if we had made a space for a vanguard, who can move ahead of the pack and teach us all the way to go? Maybe the Innovation Center can be a home for that kind of pioneering element on our behalf, on everyone's behalf. Not specialty entitled players, but our scouts.
>
> The core to me is authenticity. As I said, I think there will be parties out there who wish to take advantage of the law and the vocabulary to relabel what they already do. To repackage the status quo. I don't think that will be enough. Not at scale. We are going to have to find a way to deliver care better. And that means change.

Overview of the Proposed Rule

It is apparent that significant intergovernmental agency cooperation and coordination has gone into the production of the proposed rule, including among CMS, OIG, DOJ, FTC and IRS.[6] The extensive preamble provides a wealth of information about CMS's thinking about the various provisions of the proposed rule, options the agency considered, and where it is interested in further comments. The result will not satisfy all stakeholders, but it constitutes a comprehensive effort that will help (1) create more consistency in the treatment of these issues by regulators, (2) foster a better understanding by the industry of what is required by CMS and the other agencies and (3) indicate how enforcement agencies will view ACO activities in both the Medicare and commercial markets. Moreover, stakeholders have until June 6 to provide comments to CMS on the proposed rule (and to CMS/OIG on the waiver designs), with May 31 as the deadline for comments to the FTC/DOJ and the IRS. It is important that those interested in the long-term success of ACOs as part of the broader movement to accountable care avail themselves of this opportunity to comment.

As an initial approach to assessing the proposed rule and its impact, this article examines five key questions that I believe will be determinative of the effectiveness of the proposed rule and the success of the MSSP:

1. How well do CMS's requirements for ACO structure and governance balance the need for both flexibility and real change?

2. Does the way CMS handles provider risk, from both a financial and regulatory perspective, encourage ACO formation and participation in the MSSP?

3. Will the nature of the ACO-beneficiary relationship established under the proposed rule help avoid another managed care backlash?

[4] See Douglas A. Hastings, ''The Timeline for Accountable Care: The Rollout of the Payment and Delivery Reform Provisions in the Patient Protection and Affordable Care Act and the Implications for Accountable Care Organizations,'' *BNA's Health Law Reporter*, Vol. 19, No. 431 (March 25, 2010) (19 HLR 431, 3/25/10).

[5] ACA § 3022, as amended § 10307.

[6] *Supra* note 2; Waiver Designs in Connection with the Medicare Shared Savings Program and the Innovation Center, 76 Fed. Reg. 19,655 (notice provided April 7, 2011); Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program (March 31, 2011); and IRS Notice 2011-20 (March 31, 2011).

  HLR ISSN 1064-2137

4. Does the proposed rule advance the ball in measuring and promoting value in health care?
5. How well has CMS balanced the need to incentivize positive collaboration among providers to form effective ACOs, while also coordinating with the OIG, DOJ, FTC, and IRS in connection with their ongoing enforcement of the various laws regulating ACO participants?

Structure and Governance

The skill of CMS in providing flexibility to accommodate multiple ACO models, experimentation, and continued progress over time, while also assuring progress in the short run, is a key issue in assessing the proposed rule.

One of the much anticipated questions about CMS's rulemaking regarding ACOs was whether current health care providers would need to form new entities in all cases in order to participate in the MSSP. The answer in the proposed rule is no. However, an entity that applies to CMS to be recognized as an ACO will need to meet all of the requirements contained in Section 3022 of the ACA as well as those set forth in the proposed rule. And the applying entity cannot be virtual—it must be organized under state law and have a taxpayer identification number. Qualifying ACOs will, according to the proposed rule, be required to have a fairly comprehensive compliance plan in place to address how the ACO will comply with all legal requirements.

Each qualifying ACO legal entity will be required to enter into a three-year agreement with CMS that will place a full set of significant obligations on the ACO related to the MSSP and will include grounds for early termination of the agreement by CMS. Sixteen separate grounds for such early termination are listed in the proposed rule. Organizations interested in participating in the MSSP, including those believing that they already contain the necessary provider components, will need to reflect on what entity within their corporate family will best serve as the ACO or, indeed, whether a newly formed entity will work better, given the particulars of the proposed rule.

Among the more interesting provisions in the proposed rule are those relating to ACO governance. The governing body of a qualifying ACO must include participating ACO providers and suppliers (defined collectively as ACO participants), or their representatives, as well as at least one Medicare beneficiary representative. While no exact number of total governing body members is set forth in the proposed rule, at least 75 percent control of the governing body must be held by ACO participants, and each ACO participant must have ''appropriate proportionate control'' over governing body decision making. The reason given for this is to lessen the influence of outside entities in ACO governance. These governance representational requirements will raise practical questions about the implementation of appropriate proportionate control as well as fiduciary duty considerations for members of ACO governing bodies, who, in accordance with general corporate law principles, will owe their duty to the ACO, not the group or groups they are ''representing'' in accordance with the proposed rule.

The structure and governance sections of the proposed rule also include requirements related to ACO leadership and management. The key components in this regard are: executive leadership under the control of the governing body with a leadership team capable of achieving ACO goals; a senior-level medical director; a clinical integration program to which participating providers are committed; a physician-directed quality assurance and process improvement committee; evidence-based clinical practice guidelines; and information technology that enables the ACO to collect and evaluate data. These kinds of requirements, along with the many other infrastructure requirements set forth in the proposed rule, create a substantial minimum level of capability for an organization to qualify for inclusion in the MSSP.

Much of the debate about ACOs relates to what the minimum level of care coordination and measurement and reporting capability an ACO should have—how wide ''to cast the net.'' What we will find out as the MSSP unfolds—and a key determinant of its success—is how many earlier stage organizations that want to become ACOs will be able to meet the various minimum CMS requirements and how many of the more advanced organizations that can potentially meet them actually want to be a Medicare ACO, based on their analyses of the financial implications.

Provider Financial Risk

No one wants a repeat of provider-sponsored organizations.[7] Figuring out how to move to greater adoption of risk models today given the widespread and widely publicized failures of the 1990s remains an area of concern. Clearly, the internal debate at CMS over whether or not to allow any risk in the MSSP—and, if so, how—was an important component of the development of the proposed rule.

Under the proposed rule's provisions, ACOs can choose one of two tracks. Track 1 is bonus only for the first two years and then moves to a two-sided risk model in year three. Track 2 is a two-sided risk approach from the outset. Track 2 ACOs will need to procure reinsurance, lines of credit or other means to satisfy CMS that it can repay any losses, but the amount of shared loss is capped (at lower amounts in the early years). For Track 1, the savings allocation is 50/50 between Medicare and the ACO. In Track 2, the ACO can receive up to 60 percent. Higher potential payments are available to ACOs that achieve higher quality performance. Both Track 1 and Track 2 ACOs are subject to a 25 percent withhold. There are additional financial incentives for ACOs that include Federally Qualified Health Centers and/or rural health centers in their networks.

The possibility of state insurance regulation of provider risk sharing in connection with the MSSP is raised, but not answered—unfortunately, in my view. Comments on this issue are requested. Notwithstanding statutory authority to consider partial capitation arrangements, CMS did not include a partial capitation arrangement in the proposed rule. However, in the preamble, CMS indicates that it intends to test partial capitation arrangements through the Center for Medicare and Medicaid Innovation.[8]

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[7] *See, e.g.*, 42 U.S.C. § 1395w–25(a) (requiring a PSO to be licensed by a state as a risk-bearing entity).

[8] ACA § 3021, as amended § 10306.

Please see the following chart for a summary of how shared savings and risk works under the proposed rule:

	Track One Model (Years 1 and 2)	Track Two Model
Maximum Sharing Rate	52.5%: Sharing Rate of up to 50% Based on Quality Performance + 2.5% Maximum Sharing Rate Incentive for FQHC/RHC Participation	65%: Sharing Rate of up to 60% Based on Quality Performance + 5% Maximum Sharing Rate Incentive for FQHC/RHC Participation
Minimum Saving Rate	2 – 3.9%: Dependent on the Number of Patients Attributed to the ACO (e.g., Smaller ACOs have a Higher Minimum Savings Rate)	2%
Minimum Loss Rate	Not Applicable	2%
Shared Savings Cap	7.5% of the ACO's Benchmark (An ACO's Benchmark is the Amount CMS Estimates would have been Spent for the Attributed Patients in the Absence of the ACO, Updated by the National Spending Trend)	10% of the ACO's Benchmark
Shared Losses Rate	Not Applicable	1 – Shared Savings Rate (Reflecting the Need Not to Penalize an ACO with a Higher Shared Losses Rate because it Performs Better on the Quality Measures or Includes a FQHC/RHC)
Shared Losses Cap	Not Applicable	5% of the ACO's Benchmark in Year One, 7.5% of the ACO's Benchmark in Year Two, and 10% of the ACO's Benchmark in Year Three
Withhold	25% of Any Shared Savings Payment	25% of Any Shared Savings Payment

These are complicated sections, and the jury is out as to how well this all will work. Already, we are seeing concerns being expressed as to the feasibility and attractiveness to providers of these provisions.[9] And the degree of state insurance regulation for ACOs participating with CMS in the MSSP remains unclear. We can expect significant comment to CMS regarding the provider risk elements of the proposed rule.

ACO—Beneficiary Relationship

The method by which Medicare beneficiaries are assigned or attributed to ACOs has been greatly debated and has been the subject of many comments submitted to CMS. Proponents of both prospective and retrospective attribution argue that their approach is in the best interest of patients and will lessen the likelihood of patient backlash. The ACA puts a priority on patient choice. Would open interaction between ACOs and their assigned beneficiaries contribute to more informed consumers actively participating in their health care and, thus, better health, or will it lead to a perception of ''bureaucratic control'' and resistance from patients? Would retrospective attribution result in fairer treatment of all ACO patients and avoid the creation of two classes of patients or will it make quality and cost improvements more difficult? MedPAC, in its comments to CMS,[10] supported the prospective approach, as did most providers, but MedPAC's discussion of a potential ''opt out'' for beneficiaries shows the kind of complex issues that arise.

In the proposed rule, beneficiaries are assigned to ACOs retrospectively, based on their utilization of services by primary care physicians, defined as those in general practice, internal medicine, family practice and geriatric medicine. Specifically, Medicare beneficiaries are ''assigned'' to an ACO at the end of the reporting year if, upon review of all of the primary care services, a Medicare beneficiary received during the reporting year most of his or her primary care services from a primary care physician who is an ACO participant. In other words, a Medicare beneficiary does not have to receive a majority of his or her primary care services from an ACO primary care physician participant, but must only receive more primary care services from an ACO primary care physician participant than he or she received from any other primary care physician. Thus, ACOs will need to show that they have enough of these practitioners in their network to qualify for the MSSP.

In an attempt to add a prospective element, there will be a methodology to provide aggregate data to the ACO on the ACO's expected assigned population, and ACO providers are required to provide notice to beneficiaries that they are participating in the MSSP. Upon an ACO's request, CMS will share beneficiary claims data to assist the ACO with managing population health, coordinating care, and improving the quality and efficiency of

[9] See Steven Lieberman, *Proposed CMS Regulation Kills ACOs Softly*, Health Affairs Blog (April 6, 2011), http://healthaffairs.org/blog/2011/04/06/proposed-cms-regulation-kills-acos-softly/ (last accessed April 11, 2011).

[10] Letter from MedPAC to Donald M. Berwick, CMS Administrator (Nov. 22, 2010).

   ISSN 1064-2137

care. The ACO may only receive data from CMS for Medicare beneficiaries who have been seen by a primary care physician ACO participant during the performance year, have been informed how the ACO intends to utilize the data, and have not opted out of having their Medicare claims data shared with the ACO.

Primary care physicians within the ACO must provide Medicare beneficiaries with a form allowing each Medicare beneficiary to opt out of having his or her claim data supplied to the ACO. Finally, prior to receiving the claims data from CMS, which includes data regarding, for instance, the Medicare Part D prescription drugs that the Medicare beneficiary takes and other providers the Medicare beneficiary accesses, the ACO must execute a data use agreement with CMS that requires the ACO to adhere to the requirements of the HIPAA privacy rule and subjects the ACO to penalties for misuse of any claims data provided by CMS.

The above combination of retrospective attribution, data sharing, and notice to consumers was an effort to balance the widely divergent commentary received by CMS on these issues, as well as CMS's interpretation of Section 3022 and its reflections on the lessons of the physician group practice (PGP) demonstration.[11] Only time will tell how well it works.

Measuring and Promoting Value

If there is a consensus around any single concept in payment and delivery reform, it is that we must move from volume-based to value-based payment. Thus, one key element of the MSSP will be how it goes about measuring quality over cost and how it seeks to incent providers to deliver improved value. There is widespread agreement that evidence-based medicine and performance measurement have advanced greatly, but disagreement as to whether current data and measures are sufficient to judge ACO performance and to fairly drive both improved quality and cost savings.[12] So the measures that CMS chooses to use at the outset are important. Will it use a fairly simple ''starter set?'' Will it provide for different or additional measures for more advanced ACOs, accompanied by different payment mechanisms? We should all be interested in whether, in the proposed rule, CMS advances the definition and measurement of value in health care in a way that triggers broad agreement and, thus, helps achieve similar consensus for purposes of Medicaid and commercial market ACOs.

The proposed rule sets forth 65 measures that span the following five quality domains: patient experience of care, care coordination, patient safety, preventive health, and at-risk population/frail elderly health. These 65 measures constitute a significant, substantive set, and are set forth in some detail in the proposed rule.

Note that these are all quality measures. There are no cost-efficiency or resource use measures included. The MSSP relies on quality scores and actual savings to determine value. As cost-efficiency measures become more well-developed and accepted, the determination of value can become more sophisticated. The approach taken in the MSSP is only a start.

To encourage early stage ACOs, the proposed rule provides that ACOs can qualify to receive payments in year one by reporting on these measures only, rather than having to achieve a specific score. In subsequent years, an ACO will be required to achieve minimum attainment levels to receive points for each measure and will receive more points depending on the amount by which the ACO meets or exceeds the minimum attainment level. CMS will aggregate the individual scores for each of the measures within the domain to achieve a domain score for that ACO. ACO participants who also are eligible for the Physician Quality Reporting Initiative (PQRI) may report data required under the PQRI through the ACO. The PQRI-eligible ACO participants may receive 0.5 percent of their total Medicare Part B allowed charges during the reporting period as an incentive payment for reporting the required PQRI data.

To assist in the reporting to CMS of quality data and to spur the adoption of electronic health records (EHRs), an ACO is required to ensure that at least 50 percent of the ACO's primary care physicians are ''meaningful users'' of EHRs by the start of the second reporting period of the three-year agreement in order for the ACO to continue to participate in the MSSP. This requirement increases the challenge of participation in the MSSP by early stage physician practice-led ACOs, notwithstanding the emphasis in Section 3022 of the ACA regarding the importance of physician group participation.

The Regulatory Oversight of Accountable Care

Much of the commentary from the health care industry about ACOs, as the debate unfolded after the appearance of this concept before, during and after the passage of the ACA, related to the need to address potential legal barriers, particularly in connection with the antitrust, fraud and abuse and exempt organization tax laws. The ACA seeks to provide affirmative financial incentives through Medicare payments to diverse providers in various stages of integration in order to achieve the quality and cost efficiency goals of accountable care while also maintaining aggressive enforcement against illegal behavior. Success in this endeavor will require careful precision in distinguishing between ''good'' collaboration and care coordination on the one hand and ''bad'' payments for referrals or agreements that violate the antitrust or exempt organization tax laws on the other.[13] Finally, all of this will need to be done in a way that creates a level playing field that operates in a consistent manner in both the public and private sectors.

Has this balance been achieved in the proposed rule? Not entirely, but the agencies collectively have taken a very important and thoughtful first step.

The legal barriers mainly are addressed in three separate issuances released March 30 in conjunction with the proposed rule: a notice with comment period titled ''Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program,'' issued by the FTC and DOJ; a notice with comment period titled ''Waiver Designs in Connection with the Medicare Shared Savings Program and the Innovation

[11] 42 U.S.C. § 1395cc–1.

[12] Robert A. Berenson, M.D., ''Moving Payment from Volume to Value: What Role for Performance measurement?'' The Urban Institute (December 2010) (http://www.rwjf.org/files/research/71568full.pdf).

[13] See Douglas A. Hastings, ''Accountable Care Organization Regulation and Enforcement: Coordinated or Siloed?'' *BNA's Health Law Reporter*, Vol. 19, No. 37 (Sept. 23, 2010) (19 HLR 1333, 9/23/10).

Center,'' issued by CMS and OIG; and Notice 2011-20, issued by the IRS. There also is corollary discussion of these issuances by CMS in the proposed rule.

In early 2009, I suggested that a rebuttable presumption be established such that ''transactions, entities, arrangements and relationships structured to bring about clinical integration through appropriate collaboration among providers to improve quality and reduce costs based on evidence-based measures'' would be presumed to be in compliance with applicable law.[14] While not formally creating a rebuttable presumption, the guidance produced by the various federal agencies regarding ACOs comes close to doing that on a *de facto* basis. In one way or another, under all of these issuances, if an ACO meets CMS's requirements to participate in the MSSP, and continues to do so over time, it receives the presumption that it ''is doing the right thing'' and the legal barriers to collaboration and care coordination are reduced.

Antitrust. The FTC/DOJ proposed statement applies to ''collaborations among otherwise independent providers'' formed after March 23, 2010. It does not apply to merger transactions, which will continue to be assessed under current merger guidelines. The key presumption made here by the antitrust agencies is that CMS's proposed eligibility criteria are broadly consistent with the indicia of clinical integration that the agencies have previously set forth and, therefore, the agencies will provide rule of reason treatment, rather than *per se* treatment, as it might under current law, if, in the commercial market, the ACO uses the same governance and leadership structure and the same clinical and administrative processes that it uses to qualify for and participate in the MSSP. In other words, for antitrust purposes, the agencies are not concerned with ACO negotiations with CMS for obvious reasons, but they may be concerned with ACO negotiations with commercial payers. Thus, the thrust of the proposed statement relates to ACO behavior in the commercial market.

The agencies go further in the proposed statement than establishing rule of reason treatment. They provide a safety zone for ACOs with less than 30 percent market share, give additional guidance as to what commercial market conduct to avoid for those with 30 percent to 50 percent market share and create an expedited but mandatory (90 day) antitrust review and approval process to qualify for the MSSP for those ACOs with greater than 50 percent market share. My read is that due to concern that a CMS-approved ACO with high market share would receive ''the benefit of the doubt'' in commercial market activities by courts, the agencies have tied MSSP participation for high market share ACOs to mandatory prior antitrust review by FTC or DOJ.

For purposes of the safety zone and the mandatory review, market share relates to any common service that two or more independent ACO participants provide in their primary service area (PSA), which is defined in an appendix to the proposed statement. The under 30 percent safety zone requires that hospital and ambulatory surgery center participants, but not physicians, be nonexclusive in the network. It also includes (1) an exception to the 30 percent market share limit for rural counties as long as the providers are non-exclusive and (2) an additional limitation for any ACO that includes a provider with more than 50 percent market share in a particular service, which requires that provider to be nonexclusive and mandates that the ACO cannot require a commercial payer to contract exclusively with the ACO. ACOs in the 30 percent to 50 percent market share range also can avail themselves of the expedited review process, but are not required to do so.

Fraud and Abuse. The main thrust of the proposed fraud and abuse waivers, which are authorized under the ACA, is to protect distribution of shared savings received by an ACO from CMS to its participating providers from the application of the Stark, anti-kickback and civil money penalty statutes. This allows ACOs that are clearly doing the right thing by qualifying for the MSSP, by meeting quality requirements, and by achieving savings to align incentives among their participating providers as they see fit without concern as to illegality under the complex fraud and abuse laws, which came to be in an era of fee-for-service medicine in which enforcement agencies viewed virtually all financial incentives to and among providers as suspect. As under the antitrust laws, ACOs in the MSSP are presumed to be on the right side of the law. Significantly, this protection for shared savings distributions does not rely on fair market value substantiation, which makes sense since share savings payments by definition are based on savings earned, not fair market value for services rendered. That said, CMS has indicated in the proposed rule that it is interested in such distributions by requiring that ACOs disclose in their applications how they intend to distribute any shared savings earned among ACO participants in order to meet the goals of the MSSP.

Many commenters had sought additional fraud and abuse protection related to the formation of ACOs. No doubt CMS and OIG will receive additional comments on that subject during the comment period on this notice.

Exempt Organization Tax Law. In Notice 2011-20, the IRS joins the fray by saying in so many words that the participation of an exempt organization in an ACO that qualifies in the MSSP is substantially related to its exempt status and should not create tax issues, either as to its underlying exempt status or unrelated business income tax. While this is not a blanket approval or safe harbor, it suggests that the IRS is in accord with the other agencies in giving an ACO that participates in the MSSP a favorable presumption. That said, there are some statements in the notice that will give exempt ACO participants and their counsel pause to reflect. The notice contains fair market value and ''proportional'' distribution language that could be viewed as more limiting from a tax standpoint than the proposed waiver in connection with the fraud and abuse laws issued by CMS and OIG. In addition, the IRS articulates much more caution on its part about ACO activity in the commercial market. Indeed, the IRS states that ''negotiating with private health insurers on behalf of unrelated parties generally is not a charitable activity.'' However, in the next sentence, the IRS states that it recognizes that certain non-MSSP activities may further or be substan-

[14] See Douglas A. Hastings, ''Addressing the Legal Issues in Achieving Quality and Cost Efficiency: The Need for a Rebuttable Presumption,'' *BNA's Health Law Reporter*, Vol. 18, No. 22 (June 4, 2009) (18 HLR 740, 6/4/09).

   ISSN 1064-2137

tially related to an exempt purpose. In the end, the IRS does not take a position on exempt organization participation in ACO non-MSSP activities and asks for comments on this issue. This is thus an important area for further commentary because, as in antitrust, consistent treatment of ''good'' collaboration that enhances patient outcomes, patient satisfaction and cost efficiency in both the public and private sectors is important to the long-term success of ACOs and the widespread implementation of more coordinated care.

Conclusion

CMS and the other federal agencies involved have taken a hugely complex subject critical to the nation's financial health and the health of its population, have interpreted a specific statutory provision within the context of many others relating to accountable care, have considered thousands of comments, and have set forth a comprehensive program in proposed form for all of us to review, digest, and comment upon if we wish to do so. There will be many criticisms of the proposed rule along the lines of comments already received as well no doubt as new ones. The questions as to whether the MSSP will be successful and whether Medicare payment and delivery system reform will be aligned with ACO-related activities moving forward at the state level and in the commercial market remain open. We also will need to see what ACO initiatives come out of CMS's Innovation Center under Section 3021 of the ACA to get a fuller picture. We of course do not know today how many ACOs will apply or be admitted to the MSSP. But we do have a substantive proposed set of regulations to go along with a substantive statutory provision that CMS sees as a key component of implementing the triple aim of better care, better health, and lower costs. We should engage with CMS in this effort to move forward on the road to accountable care.