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Making Accountable Care a Reality:
Multiple Federal Agencies Issue Proposed Guidance on the Medicare Shared Savings Program

April 7, 2011

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 for public comment a much-anticipated Notice of Proposed Rulemaking ("CMS NPRM") implementing the voluntary Medicare Shared Savings Program ("Program"), which allows federally recognized accountable care organizations ("ACOs") to participate in the Program. The Program was established by Section 3022 of the Patient Protection and Affordable Care Act ("ACA"). On the same day, the Department of Health and Human Services' Office of Inspector General ("OIG"), along with CMS, released a Notice with Comment Period ("OIG/CMS Notice") to solicit comments regarding proposed waivers from the federal health care program fraud and abuse laws for provider payments made in connection with the Program.

The CMS NPRM and the OIG/CMS Notice were published in the April 7, 2011 issue of the *Federal Register*. Comments are due to these agencies on or before June 6, 2011.

Also on March 31, the Federal Trade Commission ("FTC") and the Department of Justice ("DOJ") issued a Notice with Comment Period soliciting comments regarding a "Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program" ("Proposed Statement"). The Internal Revenue Service ("IRS") also issued a notice outlining its analysis of tax-exempt organization participation in Medicare ACOs ("IRS Notice"). In addition, the IRS is seeking comments on whether any further guidance would be appropriate and whether the IRS should analyze tax-exempt organization participation in non-Medicare shared savings activities.

The IRS and FTC/DOJ also have provided the public with the opportunity to submit comments on or before May 31, 2011.

Doug Hastings

Even though the various proposed regulatory issuances will not satisfy all stakeholders, it is apparent that significant intergovernmental agency cooperation and coordination went into the production of these government issuances, and there was a concerted effort to create more consistency in the treatment of the relevant issues. Those stakeholders with issues in these proposed regulations should avail themselves of the opportunity to submit comments to the applicable agencies.

Parties interested in the Program should take the opportunity to provide the various government agencies with their input and comments on these proposed provisions.

There was no legislative history created when ACA was enacted. Consequently, it is particularly important for the public to review these proposed regulations and comment, where appropriate. Through commenting, the public has the opportunity to shape the law so that it better intersects with the health care industry's real world realities.

This alert is the first in a series that will examine these regulatory issuances as well as future government pronouncements, including those currently being formulated by the Center for Medicare and Medicaid Innovation under Section 3021 of ACA.

Eligibility and Contractual Requirements[1]

An ACO is primary care-centric but may consist of a variety of additional provider types, including, but not limited to, specialist physicians, hospitals, physician assistants, home health agencies, hospices, and nurses. However, the ACO must have a sufficient number of primary care physicians so that at least 5,000 beneficiaries are assigned to the ACO, utilizing the methodology discussed below. Primary care physicians are required to be exclusive to one ACO because an ACO is accountable for all Medicare Part A and Part B expenditures for the Medicare beneficiaries assigned to it. In addition, the assignment of beneficiaries is determined by whether the beneficiary's primary care physicians are participating in an ACO. On the other hand, non-primary care physician ACO participants may join multiple ACOs, and an ACO may not require non-primary care physician participants to be exclusive to the ACO.

What we will learn as the program unfolds – and a key determinant of its success – is how many organizations that want to become ACOs are able to meet the various minimum requirements, and how many organizations that can potentially meet them want to be a Medicare ACO, based on their analyses of the financial implications. – **Doug Hastings**

Entities seeking to become ACOs will be required to submit an application to CMS. The applicant will be required to certify that the providers and suppliers that are part of the ACO will be accountable for, and report to, CMS on the quality, cost, and overall care of the beneficiaries assigned to the ACO. Additionally, if two or more independent ACO participants have a collective market share of greater than 50 percent for any common service in those participants' "Primary Service Area" and if the ACO does not qualify for the "Rural Exception," the ACO must request an antitrust review from the FTC or DOJ. See discussion below under "Antitrust Guidance."

Supporting documentation that must be submitted to CMS with an ACO application includes:

- ACO documents, such as participant agreements or employment agreements that describe ACO participants' rights and obligations in the ACO, including how shared savings are to be distributed;
- documents describing the scope and scale of the quality assurance and clinical integration program;
- documents describing the ACO's organizational and management structure;
- evidence that the ACO has a board-certified medical director;

1 Medicare Shared Savings Program: Accountable Care Organizations," CMS Notice of Proposed Rule Making, 76 Fed. Reg. 19,528, 19,537-19,553 (April 7, 2011)(to be codified at 42 C.F.R. § 425.5).

- information regarding all of the ACO participants;
- documentation regarding how the ACO will achieve "patient centeredness," as described below; and
- evidence that the ACO has a governing body that adheres to the structural requirements described below.

Upon request, an ACO must submit documents to CMS that demonstrate the ACO's formation and operations. Such documents may include:

- charters;
- bylaws;
- articles of incorporation, a partnership agreement, or a joint venture agreement;
- management or asset purchase agreements;
- financial statements;
- a description of the remedial process that will apply if an ACO participant fails to comply with the ACO's internal procedures and performance standards, and the circumstances under which expulsion from the ACO could occur;
- a description of how the ACO will partner with community stakeholders; and
- written standards for Medicare beneficiary access to their medical records and Medicare beneficiary communications.


Shawn Gilman

An ACO may terminate its agreement with CMS prior to the completion of the three-year term by providing 60 days' prior notice to CMS and the ACO's participants and notifying its assigned Medicare beneficiaries, utilizing marketing materials approved by CMS. However, upon such a termination, the ACO would forfeit its 25-percent withhold of shared savings.

An ACO accepted into the Program by CMS must execute a three-year agreement with CMS. This agreement will require the ACO to comply with all of the Program's requirements. All agreements between the ACO and other individuals or entities that relate to ACO activities must require compliance with the Program's requirements, and the ACO must provide a copy of the ACO's three-year agreement with CMS to such other individuals or entities.

Of note, CMS Administrator Dr. Donald M. Berwick's "Triple Aim" is included in the proposed regulations in that ACOs must "establish partnerships with community stakeholders in order to advance the three-part aim of *better care for individuals, better health for populations, and lower growth in expenditures.*" An ACO must submit information to CMS that demonstrates the ACO's leadership and management structure's alignment with this Triple Aim.

From a medical review perspective, the proposed Program requires each ACO to:

- have a full-time senior medical director to provide clinical management and oversight;
- have a physician-directed quality assurance and process improvement program that establishes internal performance standards;

If an organization is looking for more information about what has worked in the ACO space to date, they should review what has taken place in the Physician Group Practice Demonstrations, which are mentioned several times in the Proposed Rule's preamble as being the source for certain positions taken by CMS. **– Lynn Shapiro Snyder**

- have processes and procedures in place to identify and correct poor compliance with such standards;
- implement evidence-based clinical guidelines for delivering care consistent with the Triple Aim; and
- have the ability to assess data and provide feedback to ACO participants, including the provision of information at the point of care to influence care.

These governance representational requirements will raise 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.
– Doug Hastings

Participants in the ACO must agree to adhere to the guidelines and be subject to performance evaluations and potential remedial actions, including expulsion from the ACO. Participants also must have a meaningful commitment to the ACO's clinical integration program. Such a commitment may be evidenced by a meaningful financial or time and effort investment in the ACO.

Finally, an ACO must be a legal entity capable of receiving and distributing shared savings, repaying shared losses, and reporting quality performance data. The governing body of the ACO must be comprised of ACO provider/supplier participants or their designees who must have at least a 75-percent control of the governing body. The governing body of the ACO also must include Medicare beneficiary representatives – a requirement reminiscent of the community representative requirement for federally qualified Health Maintenance Organizations ("HMOs"). If the ACO is comprised of multiple independent entities, the governing board must be separate and unique to the ACO (*e.g.*, an ACO consisting of a hospital and a large independent primary care group practice could not have the same governing body as either the hospital or the primary care group practice).


Mark Lutes

Potential applicants will want to apprise CMS of the substantial issues posed by the language requiring the "appropriate control over governing body decision making" for all ACO participants, irrespective of such participants' investment interest in the ACO.

Patient-Centeredness Criteria[2]

With its ACO application, an ACO must provide CMS with documentation describing how the ACO will do the following:

- promote evidence-based medicine;
- promote Medicare beneficiary engagement;
- internally report quality and cost metrics; and
- coordinate care.

Furthermore, an ACO must demonstrate patient-centeredness by:

- utilizing a Medicare beneficiary experience of care survey;
- involving ACO-assigned Medicare beneficiaries in ACO governance;
- evaluating the health needs of the ACO's assigned population, including a consideration of the diversity of its patient population;

2 *Id.* at 19,547-19,551 (to be codified at 42 C.F.R. § 425.5 (d)(15)).

- having systems in place to identify high-risk individuals and processes to develop individualized care plans for targeted populations;
- having mechanisms in place for coordinating care, such as the deployment of enabling technologies or the engagement of care coordinators;
- communicating clinical knowledge and evidence-based medicine to Medicare beneficiaries in an understandable manner;
- allowing Medicare beneficiaries to make decisions utilizing the shared-decision making process; and
- measuring clinical process by physicians across practices and utilizing the data to improve care over time.

Lesley Yeung

While the benefits of engaging patients in the decision-making process are generally well accepted, this is not a concept that is easily implemented. Instead, it will require investment in training ACO participants to change the way they interact with patients.

Shared Savings and Shared-Loss Payments[3]

Eventually, all ACOs will be required to assume the risk of shared losses. However, each ACO has the option, upon entering the Program, to choose whether the ACO will be subject to shared-loss risk during its initial reporting year. An ACO that does not want to assume shared-loss risk initially has the option of choosing "Track 1" during the ACO's first two years of participation. During the first two years of participation, a Track 1 ACO is not subject to shared-loss risk and only shares in any savings generated that exceed the minimum savings rate, assuming that quality metrics are met. In the first two years of a Track 1 ACO's participation in the Program, depending on the ACO's quality scores, the ACO is eligible to share up to 50 percent of the savings achieved.

"Savings" is defined as the difference between (A) actual Parts A and B spending during the relevant time period, and (B) the CMS predetermined spending "benchmark" for the particular ACO that exceeds the minimum savings rate threshold. An ACO's sharing rate may be increased by up to 2.5 percent, for a total possible savings rate of 52.5 percent, if the ACO includes rural health clinics ("RHCs") or federally qualified health centers ("FQHCs") and the ACO's beneficiaries receive care at the RHCs or FQHCs. A total savings payment to an ACO is limited to 7.5 percent of the ACO's benchmark that is predetermined by CMS.

A Track 1 ACO's minimum savings rate varies between 2 percent and 3.9 percent, depending on the number of Medicare beneficiaries assigned to the ACO, with a lower level of Medicare beneficiaries correlating with a higher minimum savings rate (*e.g.*, an ACO with 5,000 Medicare beneficiaries will have a minimum savings rate of 3.9 percent, and an ACO with 60,000+ Medicare beneficiaries will have a minimum savings rate of 2 percent). Certain ACOs with less than 10,000 assigned beneficiaries do not have to exceed the minimum savings rate in order for the ACO to participate in the shared savings. In its third year, a Track 1 ACO would be transitioned to the "Track 2" payment methodology wherein it would be subject to shared losses. Such an

It is clear that CMS is encouraging, and ultimately expecting, risk assumption for losses. Providers sitting out the first go-round of CMS contracting may find themselves having to assume a risk of losses from the start in the next round of ACO contracting.

Carrie Valiant

3 *Id.* at 19,602-19,624 (to be codified at 42 C.F.R. §§ 425.5 (d)(6) and 425.7).

ACO will be treated as a year-one Track 2 ACO in its first year in the Track 2 payment methodology.

Track 2 ACOs share in savings and losses generated that exceed a minimum savings/loss rate of 2 percent. The ACO may share in savings and losses at a rate of 60 percent, depending on its quality scores. A Track 2 ACO's sharing rate may be increased to 65 percent if the ACO includes RHCs or FQHCs. A total savings payment to a Track 2 ACO is limited to 10 percent of the ACO's benchmark. Additionally, a Track 2 ACO's shared losses are limited to 5 percent in year one, 7.5 percent in year two, and 10 percent in year three. A Track 2 ACO must obtain reinsurance, place funds in escrow, obtain surety bonds, or establish a line of credit as evidenced by a letter of credit that CMS can draw upon in order to ensure repayment of shared losses. Finally, both Track 1 and Track 2 ACOs' shared savings payments will be subject to a 25 percent withhold to help ensure repayment of any future losses.

Retrospective attribution of Medicare beneficiaries to an ACO was one of the surprises in the Proposed Rule, as there was general consensus that there would be prospective attribution so that ACO participants could target the coordination of care and Medicare beneficiary engagement to those Medicare beneficiaries "assigned" to the ACO. With retrospective attribution, the ACO is going to have to target all Medicare beneficiaries because the ACO will not definitively know which Medicare beneficiaries it will be assigned. **– Shawn Gilman**

Medicare Beneficiary Attribution[4]

Medicare beneficiaries are "assigned" to an ACO at the end of the reporting year (*i.e.*, retrospectively) 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. An ACO provider must post signs in each of its facilities regarding one's participation in the Program and provide written notification to inform each Medicare beneficiary of such provider's participation in the Program.

Quality Measures[5]

To share in any savings generated, an ACO must meet certain quality requirements. In year one, an ACO is only required to report on 65 measures that span these five quality domains:

- patient experience of care;
- care coordination;
- patient safety;
- preventive health; and
- at-risk population/frail elderly health.

The requirement that 50 percent of the ACO's primary care physicians must be a "meaningful user" of EHRs by the beginning of year two may prove to be a substantial roadblock to participation for those ACOs that do not have access to the needed capital. **– Shawn Gilman**

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.

4 *Id.* at 19,562-19,568 (to be codified at 42 C.F.R. § 425.6).
5 *Id.* at 19,568-19,602 (to be codified at 42 C.F.R. §§ 425.8 - 425.11).

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 .5 percent of their total Medicare Part B allowed charges during the reporting period as an incentive payment for reporting the required PQRI data.

These requirements for data sharing will delay the onset of appropriate population health management activities, thereby limiting the ability of the ACO to manage care and transitions until after a beneficiary has had a primary care physician encounter during a performance year. **– Mark Lutes**

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 Program.

Data Sharing[6]

Upon an ACO's request, CMS will share Medicare beneficiary claims data to assist the ACO with managing population health, coordinating care, and improving the quality and efficiency of 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.

As the use of special audit contractors spreads across Medicare and Medicaid programs, it will be interesting to see the extent to which CMS will engage one of these special audit contractors to monitor and assess ACO performance. **– Lesley Yeung**

CMS Monitoring of ACOs[7]

CMS will deploy a multitude a methods to monitor and assess the performance of ACOs, including analysis of the application and data that ACOs submit, site visits, investigation of beneficiary and provider complaints, and claim and chart audits. CMS is particularly concerned that ACOs will attempt to cherry-pick patients and avoid at-risk Medicare beneficiaries. If an ACO is found to be avoiding at-risk Medicare beneficiaries, the ACO may be required to: enter into a corrective action plan; forgo any shared savings during the probation period; or be terminated if, during or after the corrective action plan, the ACO continues to avoid at-risk Medicare beneficiaries. A termination by CMS under these circumstances is subject to reconsideration if requested by the ACO.

CMS will also monitor ACO compliance with the quality performance standards. The first time an ACO fails to meet a quality standard, the ACO will be given a warning. If the ACO continues to fail

6 *Id*. at 19,554-19,560 (to be codified at 42 C.F.R. § 425.19).
7 *Id.* at 19,624-19,628 (to be codified at 42 C.F.R. §§ 425.12 - 425.16).

to meet the quality performance standard, CMS may terminate the ACO from the Program, and such a termination is not appealable.

Additionally, CMS may terminate ACOs and ACO participants for:

- failing completely and accurately to report information;
- failing to comply with the eligibility requirements;
- failing to provide Medicare beneficiaries with notification that the provider is an ACO participant;
- failing to submit an approvable corrective action plan or failing to implement such a plan;
- violating the federal health care program fraud and abuse or antitrust laws;
- failing to maintain an assigned Medicare beneficiary population of at least 5,000 beneficiaries;
- failing to offer Medicare beneficiaries the option to opt out of the sharing of their claims data;
- improperly disclosing information regarding patients; or
- failing to demonstrate that the ACO has adequate resources to repay shared losses.

Terminations by CMS pursuant to the acts listed above are subject to reconsideration if requested by the ACO.

There are several different types of opportunities for health care organizations to attempt to obtain additional payments to offset expected Medicare reductions arising from health reform. ACO development may work for some organizations, but others may find the customization opportunities from the Center for Innovation or the National Pilot Program on Payment Bundling to be more compatible with an organization's starting point. – **Lynn Shapiro Snyder**

I'm heartened that there is broad protection for downstream distributions of shared savings payments, so ACOs can align incentives with their ACO providers. Significantly, this broad protection for shared savings distributions does not seem to rely on fair market value substantiation. This makes good sense, since shared savings payments, by definition, are based on savings, not on fair market value for services rendered. – **Carrie Valiant**

David Matyas

Their proposal to adopt a broad waiver, instead of requiring parties to either seek an advisory opinion or obtain an individual waiver for a particular program, should be lauded. These agencies have demonstrated their understanding that creating limited exceptions to these laws, which were adopted to address fraud, waste, and abuse in a fee-for-service payment system, would be impractical under a system that is attempting to reward providers for quality of care while also encouraging reduction in costs.

Overlap with Other Shared Savings Programs[8]

So as not to double count savings, Medicare providers and suppliers may not participate in ACOs that are in the Program if they are already participating in the Independence at Home Pilot Program, a Center for Medicare and Medicaid Innovation initiative that involves shared savings, or any other Medicare initiative that involves shared savings.

Fraud and Abuse[9]

One of the key compliance issues for ACOs is the extent to which its financial relationships with providers/supplier participants and Medicare beneficiaries are in compliance with the existing federal health care program fraud and abuse laws. Although CMS and OIG have not proposed any specific waiver language, the agencies have requested comments regarding proposed waivers from the Physician Self-Referral ("Stark")

8 *Id.* at 19,631-19,632 (to be codified at 42 C.F.R. §§ 425.24).

9 *Id.* at 19,628; *see also* "Medicare Program: Waiver Designs in Connection with the Medicare Shared Savings Program and the Innovation Center," 76 Fed. Reg. 19,655 (April 7, 2011).

It is refreshing to see these agencies willing to state, at least in the context of these regulations, that compliance with an exception under the Stark Law will protect financial relationships under anti-kickback and civil monetary penalty laws. – **David Matyas**

Law, the Federal Anti-Kickback Statute, and certain provisions of the Civil Monetary Penalty Law to facilitate ACO development.

The agencies suggest in the notice that they are proposing to waive the Stark Law and the Federal Anti-Kickback Statute for shared savings that CMS pays to an ACO that are then distributed to ACO participants, providers, or suppliers for the year that shared savings are earned. The Stark Law and Federal Anti-Kickback Statute also are waived for shared savings distributions (including those made outside the ACO) that are directly related to the ACO's participation in, and operations under, the Program. The agencies have suggested that shared savings distributions should also qualify for a waiver from the civil monetary penalty prohibiting hospital payments to physicians to reduce or limit care if both the hospital and physician are ACO participants and the payment is not knowingly made to induce the physician to reduce or limit medically necessary care.

The lack of any exception from the civil monetary penalty for beneficiary inducements is an area that needs work, in light of the quality measures contemplating that patients adhere to certain care requirements. Just because the physicians prescribe it, doesn't mean the patients will follow it. Fortunately, the OIG has this on its list of follow-up areas for further comment and consideration. – **Carrie Valiant**

Financial relationships also can qualify for more limited protection if the financial relationship qualifies for an existing Stark Law exception. Specifically, the agencies have proposed that situations in which a financial relationship implicates the Stark Law and meets a Stark Law exception, the financial relationship will qualify for a waiver from the Federal Anti-Kickback Statute and the civil monetary penalty for physician payments for reduced or limited care.

Comments are specifically requested in a number of areas that suggest that the OIG is considering expanding the waiver beyond shared savings distributions to other areas related to ACO operations.

Under the CMS NPRM, CMS has also suggested that, from an operational perspective, the ACO must agree, and must require each individual and entity with which it contracts to agree, to comply with the federal health care program fraud and abuse laws. Furthermore, all marketing materials related to the ACO and changes to the same must be approved by CMS prior to use by the ACO. There are only limited exceptions for material that is limited to a subset of individuals and to beneficiary-specific or educational information on specific medical conditions.

Additionally, ACOs must have in place a compliance plan that includes at least the following: a designated compliance officer who is not legal counsel for the ACO and who has direct access to the ACO's governing body; auditing functions that have the ability to identify and address compliance issues; a reporting mechanism, such as a hotline; compliance training; and a requirement that suspected violations of law are reported to an appropriate law enforcement agency.[10]

10 *Supra* note 1 at 19,551-19,552 (to be codified at 42 C.F.R. § 425.5 (d)(10)).

Antitrust Guidance[11]


Patricia Wagner

The Proposed Statement continues the underlying theme of clinical integration – improving the quality of care while decreasing the cost of that care and developing processes to meaningfully measure that quality improvement.

Corresponding with the release of the CMS NPRM, the federal antitrust enforcement agencies released the Proposed Statement, which provides a safety zone to certain ACOs if they meet the standards required by CMS and if the ACO's independent participants do not have a collective market share for shared services of greater than 30 percent.

Notably, the market share determination must be done whenever two or more independent participants have a shared service, and the assessment must take into account each of those participants' Primary Service Area. If two or more independent ACO participants have a collective market share of greater than 50 percent for any common service in those participants' Primary Service Area, the ACO must request an antitrust review from the FTC or DOJ. The Proposed Statement details the information that must be provided to the FTC or DOJ in order to obtain the expedited review. The ACO must submit with its application to CMS a letter from either the FTC or DOJ confirming that either the FTC or DOJ does not presently intend to challenge or recommend challenging the proposed ACO.

Because all of the information that will be submitted to CMS must be included in the request for an expedited review by the FTC/DOJ, and those requests must be submitted 90 days before the last day CMS accepts applications, those entities requiring or wanting expedited review from the antitrust agencies will have less time to compile their applications. – Patricia Wagner

The Proposed Statement also provides guidance for those ACOs where two or more independent participants have a collective market share between 30 percent and 50 percent for shared services. In that guidance, the agencies identify five types of conduct that "an ACO can avoid to reduce significantly, the likelihood of an antitrust investigation." In addition, the Proposed Statement allows these ACOs to request an expedited (90-day) review of the ACO, requires all hospitals and ambulatory surgery centers to be non-exclusive, and requires any dominant provider (any provider with a greater than a 50-percent market share in its Primary Service Area) to be non-exclusive.

Tax-Exempt Issues[12]

Two fundamental concerns for most tax-exempt health care organizations are the prohibition against private inurement (*i.e.*, the flow of funds to insiders not tied to a specific returned benefit) and the prohibition against private benefit (*i.e.*, the flow of funds to private interests that exceeds the public benefit derived from the related activity). The violation of either prohibition is grounds for revocation of exemption. According to the IRS Notice, the IRS expects


Dale Van Demark

The IRS has provided a clear pathway for those tax-exempt organizations wishing to participate in the Program through an ACO.

11 *Id*. at 19,628-19,631 (to be codified at 42 C.F.R. § 425.5 (d)(2)); *see also* Federal Trade Commission and Department of Justice, "Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program" (Mar. 31, 2011).

12 *Id.* at 19,628; *see also* IRS Notice 2011-20.

that it will not find violations of either of these prohibitions when a tax-exempt organization participates in an ACO with for-profit participants in the Program if:

- the terms of the exempt organization's participation (including its share of payments or losses and expenses) are set forth in an "arm's length" negotiated agreement;
- CMS has accepted the ACO's participation in the Program (and has not terminated such participation);
- the exempt organization's share in the economic benefit and losses is proportionate to the benefit it provides, and its share of losses does not exceed its share of benefits (*i.e.*, the exempt organization cannot subsidize other participants' participation); and
- all contracts and transactions of the ACO (including, but exclusively, between the exempt organization and the ACO) are at fair market value.

> *By questioning the link between participation in a non-Medicare ACO and the exempt purpose of tax-exempt health care providers, the IRS is extending the discussion about what constitutes community benefit and challenging exempt providers to clearly articulate how the delivery and payment reforms we are seeing inform that discussion.*
> – **Dale Van Demark**

In addition, the IRS stated that no unrelated business taxable income would accrue to tax-exempt participants because participation in the Program lessens the burden of the government.

In the IRS Notice, the IRS also asked for comments regarding the appropriate analysis of the tax-exempt organization's participation in ACOs that engage in activities other than participation in the Program. The IRS stated its concern with the lack of regulatory requirements imposing quality performance and other standards and a lack of governmental oversight in non-Medicare shared savings activities.

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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Conclusion

The CMS NPRM presents opportunities and challenges for providers and suppliers that may wish to consider participating in the Program. It is a new, albeit complex, program. Consequently, it is important for all relevant stakeholders to review and submit comments to these proposed regulations to CMS and OIG by June 6, 2011, and to the IRS and FTC/DOJ by March 31, 2011.

We, of course, do not know today how many ACOs will apply, or be admitted, to the Program. 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. We should engage with CMS in this effort to move forward on the road to accountable care. – **Doug Hastings**

Seeking the status as an ACO under the proposed regulations is not for the faint of heart. It will require an organization to be sophisticated in its ability to track information, educate and train professionals and consumers on best practices, and comply with a myriad of rules incorporated into the requirements for being an ACO – **Lynn Shapiro Snyder**

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Complimentary Three Part Webinar Series:

EBG is pleased to announce that it will be co-hosting with KPMG the following complimentary three-part series of webinars concerning the regulations and government statements:

Tuesday, April 12, 2011: 12:00 pm – 1:30 pm EDT
"What Do the Regulations Say, and What Do They Mean?"

Tuesday, April 19, 2011: 12:00 pm – 1:30 pm EDT
"What Should an Organization Do to Begin to Operationalize the Regulations?"

Tuesday, April 26, 2011: 12:00 pm – 1:30 pm EDT
"Is Your Organization Ready to Be an ACO?" *

*At this webinar, EpsteinBeckerGreen and KPMG will be joined by The JHD Group

Individuals interested in registering can go to:
http://www.kpmginstitutes.com/healthcare-pharma-institute/events/aco-rules-released-what-do-they-mean.aspx

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IMPLEMENTING HEALTH AND INSURANCE REFORM:
Opportunities & Challenges for Your Organization

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