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ACOs

CMS, IRS, Antitrust Agencies Issue Proposals For ACOs Under ACA Shared Savings Program

In what some health care attorneys called an unprecedented example of federal cooperation and coordination, federal health care, tax, and antitrust law enforcement agencies March 31 released a series of long-anticipated proposals to guide doctors, hospitals, and other health care providers looking to form accountable care organizations (ACOs) and participate in the Medicare shared savings program (MSSP) under the Patient Protection and Affordable Care Act (ACA).

The centerpiece of the four proposals was a 429-page proposed rule issued by the Centers for Medicare & Medicaid Services that sets out the MSSP parameters and provides details of how CMS expects ACOs to participate in the program designed to address the current, ''fragmented'' health care delivery system and reward ACOs that lower costs while meeting quality standards.

Building on the CMS proposal, the Department of Justice's Antitrust Division and the Federal Trade Commission issued a proposed statement of antitrust enforcement policy for ACOs enunciating the agencies' general view of how ACOs can successfully participate in the U.S. health care delivery system without harming competition or consumers. They also established a regulatory framework for how the agencies will assess and approve ACOs and said that they will share responsibility for enforcement in this area.

Addressing fraud and abuse concerns, CMS and the Department of Health and Human Services Office of Inspector General jointly issued a notice with comment period outlining proposals for waivers of the physician self-referral law (known as the Stark law), the anti-kickback statute, and certain provisions of the civil monetary penalty (CMP) law in connection with the operation of ACOs under MSSP.

Finally, The Internal Revenue Service issued guidance (IRS Notice 2011-20) on the tax treatment of ACOs, saying nonprofit health care providers should be able to participate in the MSSP as long as they pay attention to traditional limits imposed on exempt organizations by federal tax laws. While IRS said exempt organizations that participate in ACOs that are blessed by CMS likely will qualify for continued exemption as entities that ''lessen the burdens of government,'' it did not address thorny ACO ''control'' issues and asked for comments on other issues that could arise if these same ACOs engage in contracting outside of the Medicare and Medicaid programs.

Uncertainties Remain. Practitioners who spoke to BNA said they were focused primarily on digesting the CMS rule, reviewing the program details both to determine the incentives and impediments their clients who want to participate in ACOs might face and because compliance with the CMS regulatory template will form the basis for gaining favorable consideration and approvals by antitrust, tax, and fraud and abuse law enforcers.

They noted that the rules, notices, and policy statement are all subject to notice and comment and that they expect affected parties to engage in a vigorous effort to weigh in with suggestions and concerns. Several noted that this is a novel endeavor for DOJ and the FTC, agencies that do not normally put their enforcement policy positions out for notice and comment.

The notice and comment period also will give the affected agencies an opportunity to adjust and refine their message, they added. Because of the uncertainties and complexities associated with the program and potential changes, practitioners said it is unclear at this point which organizations will ''jump in with both feet'' and which may take a ''wait and see approach.''

SHARED SAVINGS PROGRAM UNVEILED

The MSSP according to the CMS rule, is designed to reduce fragmented care, align payment with the most effective care, and achieve better coordinated care for Medicare beneficiaries overall. The program must be established by Jan. 1, 2012.

An ACO is a group of medical care providers that accepts responsibility for providing or arranging all care for a group of Medicare patients under a payment arrangement that allows it to profit from reducing costs and improving quality of care.

The proposed rule will be published in the April 7 *Federal Register* and comments will be accepted until June 6, CMS said.

In March 31 conference call with reporters, Health and Human Services Secretary Kathleen Sebelius said that ACOs are the vehicle proposed to meet the MSSP goals and that the government would save up to $960 million over three years under the program after all performance incentives are paid to providers. According to the rule, ACOs would, on average, save the government $510 million over three years.

''For too long, it has been too difficult for health care providers to work together to coordinate and improve the care their patients receive,'' Sebelius said in a statement.

''That has real consequences: patients have gaps in their care, receive duplicative care, or are at increased risk of suffering from medical mistakes. Accountable

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care organizations will improve coordination and communication among doctors and hospitals, improve the quality of the care their patients receive, and help lower costs,'' she said.

Under the proposed rule, providers and suppliers can continue to receive traditional Medicare fee-for-service payments under Part A and Part B and be eligible for additional payments based on meeting specified quality and savings requirements. An existing ACO will not be accepted automatically into the shared savings program, CMS said. To be accepted, they must serve at least 5,000 Medicare patients and agree to participate in the program for three years.

CMS Administrator Donald M. Berwick said the proposed rule also contains protections so that patients' choices are not limited by an ACO.

Two Models. CMS would implement both a one-sided risk model (sharing savings only for the first two years and sharing of savings and losses in the third year) and a two-sided risk model (sharing savings and losses for all three years), allowing the ACO to opt for one or the other models.

Berwick said the choice allows entities to form ACOs that are not yet ready to take on shared risk. A CMS fact sheet said the two models would have the advantage of providing an entry point for organizations with less experience with risk models, such as some physician-driven organizations or smaller ACOs, to gain experience with population management before transitioning to a risk-based model.

It would provide an opportunity for more experienced ACOs that are ready to share in losses to enter a sharing arrangement that provides a greater share of savings but at the risk of repaying Medicare a portion of any losses.

ACOs that participate in the two-sided model would be able to obtain greater savings. However, the rule also proposed to establish a minimum savings rate. ACOs in the one-sided risk program that have smaller populations (and having more variation in expenditures) would have a larger savings rate, and ACOs with larger populations (and having less variation in expenditures) have a smaller rate. Under the two-sided approach, CMS proposed a flat 2 percent minimum savings rate.

Erik Johnson, senior vice president of Avalere Health, told BNA in a interview March 31 that by offering two different tracks, CMS showed it was aware of hospitals' skepticism about the true costs and savings of forming ACOs. Johnson said there was nothing in the proposed rule that might help alleviate that skepticism, but it might provide more specific areas where hospitals can target their concerns.

Johnson also said the proposed rule would mean hospitals have to get better at managing risk if they want the financial rewards. However, he said it would be difficult for most hospitals to meet those goals in the first three years. As a result, if hospitals opt into the shared savings program, they need to have a long-term view for success, rather than short term views.

Quality Reporting. CMS said the proposed rule would establish quality performance measures and a methodology for linking quality and financial performance ''that will set a high bar on delivering coordinated and patient-centered care by ACOs, and emphasize continuous improvement around the three-part aim of better care for individuals, better health for populations, and lower growth in expenditures.''

The proposed rule would require the ACO to have in place procedures and processes to promote evidence-based medicine and beneficiary engagement in their care. The proposed rule also would require ACOs to report quality measures to CMS and give timely feedback to providers. The rule proposed 65 quality measures across five key areas: patient/caregiver care experiences, care coordination, patient safety, preventative health, and at-risk population/frail elderly health.

Under the proposed rule, an ACO that meets the program's quality performance standards would be eligible to receive a share of the savings it generates below a specific expenditure benchmark that would be set by CMS for each ACO.

The proposed rule also would hold ACOs accountable for downside risk by requiring ACOs to repay Medicare for a portion of losses (expenditures above its benchmark).

The benchmark would take into account beneficiary characteristics and other factors that may affect the need for health care services. This benchmark would be updated for each performance year within the three-year performance period.

The quality measures are aligned with the measures in other CMS programs such as the Electronic Health Records and Physician Quality Reporting System. An ACO that successfully reports the quality measures required under the shared savings program would be deemed eligible for a PQRS bonus.

However, the rule specifies that ACOs may not participate in any other shared savings program or demonstration under the Center for Medicare and Medicaid Innovation or Independence At Home Medical Practice pilot program to ensure that savings are not counted twice.

Patient Notification. Since it is providers, not patients, who choose to enroll in an ACO, CMS in the rule proposed requiring ACO providers to notify beneficiaries, at the time they seek services, that the provider is participating in an ACO.

The providers would offer beneficiaries information about the ACO, including how the ACO would improve the care that they receive. Providers in an ACO also would be required to post signs in their facilities indicating their participation in an ACO and to make available written information about the ACO to Medicare beneficiaries.

Even if a beneficiary seeks care from a physician, hospital, or other facility that is a member of an ACO, the beneficiary still would be able to choose to visit any provider they wanted.

An ACO would be prohibited from using managed care techniques such as limiting the beneficiary to certain providers, utilization management, or requiring prior authorization for services for Medicare beneficiaries.

Initial Reaction. While most health care groups said they were analyzing the impact of the proposed rule to submit comments by the June 6 deadline.

The Premier health care alliance offered comprehensive initial comments on the proposed rule. The group said it ''supports CMS in its efforts to develop people-centered, sensible regulations for accountable care organizations (ACOs). This new model of care delivery

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represents one of our best hopes for overcoming fragmentation in care delivery.''

Regarding beneficiary notification, Premier said that ''requiring that beneficiaries are made aware of their participation in the ACO will ensure transparency and provide consumers with appropriate, fact-based information on their healthcare choices. We also support CMS' decision to allow ACOs to not only contact, but also provide additional benefits and services to beneficiaries, including disease management programs and condition-specific education.''

Premier also said it was ''extremely pleased'' that CMS proposed allowing multiple payment models within the ACO program from the start.

''Different ACOs are at different points in their journey to deliver accountable care, with some prepared to participate in a one-sided shared savings program, while others are able to accept downside risk,'' Premier said. ''As ACOs are local and subject to regional market conditions, multiple payment models will allow a variety of approaches to be tested, as well as a broader scope of learnings for CMS.''

However, the group noted that ''noticeably absent from the rule are partial and full capitation payment models. We hope such options will be considered either in the final rule or through the CMS Innovation Center.''

Democratic lawmakers also weighed in on the proposed rule. Senate Finance Committee Chairman Max Baucus (D-Mont.), in a statement March 31, praised the concept of sharing best practices.

''When Medicare gives doctors, nurses and hospitals the opportunity to come together to form a team, it also gives them the opportunity to share in each other's knowledge about medicine and about their individual patient,'' Baucus said.

''Cooperation among the medical professionals on these teams reduces duplicative scans and tests, prevents unnecessary hospital stays and keeps all of a patient's caregivers more informed,'' he said. ''These new health care teams will produce better health care outcomes for patients and reduce waste, saving Medicare dollars.''

Senate Health, Education, Labor and Pensions Committee Chairman Tom Harkin (D-Iowa) said in a statement that he was ''pleased that the Department of Health and Human Services has proposed a thoughtful and balanced rule that will encourage Medicare providers across the care continuum to collaborate, which will yield better care for their patients and ultimately reduce costs both for patients and the government.''

Affect on Device Makers. The impact on medical device makers of the CMS rule is uncertain, health care analysts told BNA.

Although device industry groups expressed concerns about protecting providers' treatment choices, some analysts said the proposal is likely to have an indirect impact on device makers and could even spur innovations for medical technologies that keep patients out of the most expensive care settings.

Device industry trade groups issued statements reaffirming their support for an ACO program that protects access to innovative medical technology. The Medical Device Manufacturers Association (MDMA) and the Advanced Medical Technology Association (AdvaMed) said they will closely examine the proposed rule to assess whether it needs modification to achieve its objective.

Ian Spatz, a senior adviser for health care at Manatt, Phelps & Phillips in Washington, told BNA that because the proposed design of the integrated provider networks is so new, much about the rule that remains unknown, especially where the center of clinical authority lies.

''This precise model ... people have no experience with it,'' Spatz said, because the current private sector experiments on integrated care are reimbursed by capitation payments, and the proposed ACO system is built on top of the current Medicare fee-for-service (FFS) model.

Erik Johnson, senior vice president of Avalere Health, told BNA that any impact on device manufacturers would at first be indirect, because there is no carve-out in the proposal for device makers, and they also were not explicitly targeted.

With the emphasis being placed on ACOs reducing the cost of care while increasing quality, Johnson said, hospitals and physicians might end up cutting back on certain supplies, which could have a negative impact on devices in the short term. In the long run, however, the effectiveness of the device will matter more than price, and only a limited amount of money can be saved by cutting back on supplies, he said.

Spatz said he would not be too worried about hospitals potentially cutting back on expensive devices because the reimbursement incentives in place under Medicare would not change. If a hospital in an ACO provides a patient with a device, that hospital would get reimbursed at the same time and at the same rate as it would under current Medicare FFS.

Randy Fenninger, senior policy adviser at Holland & Knight in Washington, told BNA that ''there will be a terrible temptation'' for hospitals to stop using certain devices or to cherry-pick the least complex patients, but the proposed rule would allow the government to monitor ACOs to discourage such behavior from providers.

He said the opportunities for medical device companies ''could be great'' if the ACO concept succeeds as envisioned. ''I see this as an opportunity for innovative companies, but it won't be pain free,'' Fenninger said.

Under ACOs, ''the real bucket of money [for hospitals] is keeping people out of hospitals,'' Fenninger said. So if ACOs succeeded, it would open outpatient markets for device manufacturers, he said. Device makers would have incentives to ''create clever devices that get inpatients out of hospitals as soon as possible.''

''If device companies read the market right, they will be fine,'' Fenninger said. If not, they will be bought by the companies that adjusted, and that were ''nimble enough to shed products and divisions that aren't useful.''

ANTITRUST ENFORCEMENT POLICY

DOJ and FTC's proposed statement of antitrust enforcement policy for accountable care organizations participating in the MSSP details the two agencies' general view of how ACOs can essentially engage in joint contracting—with respect to government and private payers—without harming competition or consumers.

It also establishes a framework for how the agencies will assess and review ACOs, in conjunction with CMS approval requirements delineated in its proposed rule, and says that they will share responsibility for enforce-

ment in this area. DOJ and FTC will accept comment through May 31.

The major component of the proposed enforcement policy is the agencies' position that compliance with ACO eligibility criteria proposed by CMS will be deemed ''reasonably likely to be bona fide arrangements intended to improve the quality, and reduce the costs, of providing medical and other health care services through their participants' joint efforts.''

ACOs that have the same governance, leadership structure, and clinical and administrative processes as are required by CMS for program participation will be evaluated, with respect to their contracting with private payers, under the ''rule of reason'' analytical framework, the antitrust regulators said. A rule of reason analysis, which is less rigorous than the ''per se'' rule that generally applies to price-fixing, asks whether a collaboration of competitors ''is likely to have substantial anticompetitive effects and, if so, whether the collaboration's potential procompetitive efficiencies are likely to outweigh those effects,'' FTC and DOJ noted.

This approach is consistent with the antitrust agencies' longstanding position, memorialized in part in their 1996 Statements of Antitrust Enforcement Policy in Health Care, that joint contracting by groups of financially and/or clinically integrated health care providers does not run afoul of antitrust laws as long as the joint contracting ''is reasonably necessary to accomplish the procompetitive benefits of the integration,'' the agencies said.

The title of the DOJ-FTC document is ''Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program.''

Formal Legal Structure. In its proposed rule, CMS is requiring ACOs to have a formal legal structure that would allow them to receive and distribute payments for shared savings, leadership and management structures that include clinical and administrative processes, processes to promote evidence-based medicine and patient engagement, a system for reporting on quality and cost measures, and the ability to provide coordinated care for beneficiaries.

''The Agencies have determined that CMS's proposed eligibility criteria are broadly consistent with the indicia of clinical integration that the Agencies previously set forth in the Health Care Statements and identified in the context of specific proposals for clinical integration from health care providers,'' FTC and DOJ said.

The MSSP also will provide CMS with cost, utilization, and quality metrics on an annual basis relating to each ACO's performance, FTC and DOJ noted. ''This extensive monitoring . . . will help the Agencies determine the extent to which the proposed CMS eligibility criteria in fact lead to cost savings and improved health care quality and may help inform the Agencies' future analysis of ACOs and other provider organizations,'' the agencies added.

'Safety Zone.' The policy statement establishes what the agencies described as an antitrust enforcement ''safety zone,'' which will apply to those ACOs that obtain CMS approval; describes mandatory and voluntary agency review options; and sets forth a ''streamlined'' analytical process the agencies will use to determine whether a specific ACO raises ''significant competitive concerns.''

The policy statement said the agencies will look to evaluate an ACO's share of services in each ACO participant's Primary Service Area (PSA), which the proposal likened to a geographic market assessment used to determine potential anticompetitive effects. The agencies will assume the higher the PSA share, the greater the risk an ACO might be anticompetitive.

''An ACO with high PSA shares may reduce quality, innovation, and choice for Medicare and commercial patients, in part by reducing the ability of competing equally or more efficient ACOs to form. High PSA shares also may allow the ACO to raise prices to commercial health plans above competitive levels,'' the agencies noted.

Based on this PSA-based approach, the agencies said, they will not normally challenge CMS-approved ACOs in which ''independent ACO participants (e.g., physician group practices) that provide the same service (a 'common service') . . . have a combined share of 30 percent or less of each common service in each participant's PSA, wherever two or more ACO participants provide that service to patients from that PSA.''

The policy statement also requires that a hospital or ambulatory surgery center (ASC) participating in an ACO ''must be non-exclusive to the ACO to fall within the safety zone, regardless of its PSA share.'' In the nonexclusive context, ''a hospital or ASC is allowed to contract individually or affiliate with other ACOs or commercial payers,'' the proposal said.

FTC and DOJ also set forth a ''rural exception,'' which allows nonexclusive arrangements with certain physicians in rural areas, even though the inclusion of that physician would cause the ACO to exceed the 30 percent common service threshold, and a ''dominant provider limitation,'' which applies a ''non-exclusivity'' requirement to any ACO participant with greater than a 50 percent share in its PSA of any service that no other ACO participant provides.

Agency Reviews. The DOJ and FTC detailed mandatory review requirements applicable to ACOs, other than those in rural areas, with participants whose shares exceed the 50 percent threshold, and voluntary review opportunities for ACOs falling between the 30 percent and 50 percent thresholds that desire ''certainty'' regarding the antitrust implications of their configuration in a particular market.

The agencies said reviews would be coordinated by an interagency work group and performed on an expedited basis—with an aim to completion within a 90-day period—for mandatory and voluntary review requests.

Mandatory review is required under the CMS proposal before an ACO with participants whose shares exceed the 50 percent threshold may qualify for MSSP participation. The agencies set forth extensive documentation requirements and described the information that an ACO will have to show to earn antitrust agency approval. Voluntary review may be obtained following the same procedures outlined with respect to mandatory review, the agencies said.

Voluntary review may be unnecessary, however, if the ACO avoids five specifically delineated types of conduct set forth in the proposal, the agencies said. That conduct includes:

- preventing or discouraging commercial payers from directing or incentivizing patients to choose certain providers;

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■ tying sales of the ACO's services to the commercial payer's purchase of other services from providers outside the ACO;

■ except in the case of primary care physicians, contracting with other ACO physician specialists, hospitals, ASCs, or other providers on an exclusive basis;

■ restricting the ability of commercial payers to make information on cost, quality, efficiency, and performance available to its health plan enrollees; and

■ sharing competitively sensitive pricing information or other data among the ACO's provider participants.

New Role for Agencies. Douglas Ross, with Davis Wright Tremaine LLP in Seattle, said the statement by the federal antitrust agencies will create challenges for antitrust attorneys who will help ACOs navigate the new requirements and could tax the agencies themselves.

The agencies' policy ''is a full employment act for health care antitrust lawyers'' and, with provisions mandating pre-approval ACO review, has DOJ and the FTC, which traditionally have seen themselves as enforcement agencies, taking a ''big step towards being traditional regulatory agencies,'' Ross said.

''With the exception of the Hart-Scott-Rodino premerger process and the FTC's enforcement of the Robinson-Patman Act, DOJ and the FTC enforce the antitrust laws when they discover violations; they typically do not have to grant permission before something can be done,'' Ross said. ''That's changing now—and it is an odd result for agencies that are charged with ensuring that a free market prevails.''

Ross said the promise of expedited review is welcome, but ''it remains to be seen how often applicants will be able to submit all required information without having the agencies come back, again and again, asking for more. If that happens, the idea that an expedited, 90-day review will work is in serious jeopardy.''

Ross said the 30 percent threshold in the proposal is ''generous to providers, by the agencies' previous standards, which included a safety zone for provider networks only up to 20 percent of market share.'' On the other hand, ''the rural exception that permits an ACO to enlist one physician per specialty without forcing an antitrust review if he or she is the only one in the specialty is far too conservative,'' Ross said.

He said it was ''extremely interesting'' that the agencies decided to rely on PSAs as a proxy for delineating the relevant antitrust market. ''The agencies concede in the proposal that a PSA is not the same as a relevant geographic market for antitrust purposes, but implicitly realize that, if they were to try to define antitrust markets, the administrative process would be unworkable,'' he added.

''So this is the compromise. But sometimes, the area defined by the PSA and the relevant geographic market are very different things,'' Ross said.

Ross also noted that, while being in an antitrust safety zone will protect those ACOs that receive an approval letter from an antitrust agency as long as they do not substantially change the manner in which they do business, it would provide no such protection from private litigants. ''Private parties will be free in such a situation to sue the ACO and courts will not necessarily follow the Policy Statement as it does not express antitrust law,'' Ross added.

'Impressive Feat.' Richard D. Raskin, with Sidley Austin LLP, Chicago, said the policy statement on ACOs represented ''an impressive feat of coordination among not only DOJ and FTC, but also CMS.'' It incorporates features of the proposed CMS rule that, in turn, reflects input the antitrust agencies provided, he said, adding, ''the two are designed to work hand in glove.''

Perhaps the most significant feature of the policy statement ''is the requirement for advance sign-off by a federal antitrust agency for ACOs that trigger prescribed market share thresholds,'' Raskin continued. ''That is a requirement that cannot be found in PPACA and is one that builds into CMS's approval process for ACOs a critical screening role for the antitrust agencies,'' he said.

''While the agencies have now defined their proposed thresholds for triggering antitrust review, they have not specified the market share levels that will cause them to actually bring an enforcement action, nor can they be expected to,'' Raskin continued. ''That will continue to depend on many factors, not just market share.''

''In addition, the method that the agencies propose for defining markets and measuring market shares raises many questions of its own. So while there may be some gain in clarity offered by the proposed statement, no one should think that we can now simply crunch the numbers and predict an outcome. Whether an ACO is actually challenged will continue to depend on a fact-specific, market-specific analysis,'' Raskin concluded.

Interagency Coordination 'Unprecedented.' In announcing the proposal, FTC Chairman Jon Leibowitz said four agencies—CMS/Health and Human Services, DOJ, FTC, and the Treasury Department/IRS—engaged in an ''unprecedented, collaborative effort . . . [to] ensure that ACOs meet their goals of improving quality and lowering costs while minimizing the regulatory burden on health care providers.''

The agencies said in a statement that they ''recognize that ACOs may generate opportunities for health care providers to innovate in both the Medicare and commercial markets to achieve the cost savings Congress intended'' in establishing MSSP. ''At the same time, however, the agencies also understand that collaborations among competitors—as will occur through the formation of ACOs—may raise concerns about competition,'' the statement added.

The FTC voted 4-1 to approve the proposed policy statement on antitrust, with Commissioner J. Thomas Rosch the lone dissenter. Rosch said in a statement that, although he agrees generally with the analytical framework described in the proposal, he disagrees with the decision to have both antitrust agencies involved in ACO formation review.

According to the FTC statement, ''Rosch believes that responsibility for reviewing the formation of ACOs should remain with the Commission because: 1) the Antitrust Division currently has far less expertise or experience than the Commission in reviewing the formation of ACOs or applying the antitrust laws to them; and 2) the Antitrust Division is more susceptible than the Commission, an independent agency, to lobbying and other political pressure.''

The statement said Rosch believes ''the evaluation of some ACOs by the Antitrust Division represents a vic-

tory for physicians and hospitals—as well as their lobbyists and political supporters—which have opposed Commission review and antitrust enforcement of clinically-integrated health care providers.''

Comments Requested. The proposal includes a request for comment on the suggested components of antitrust review of ACOs and asks for guidance on obtaining data needed to calculate PSA shares for certain physician services, such as pediatrics and obstetrics, rarely used by Medicare beneficiaries and data for inpatient hospital services in states where all-payer hospital discharge data are unavailable.

The agencies also asked whether being required to provide the documents and information needed to obtain expedited antitrust review will present an undue burden on ACO applicants.

Comments may be filed electronically at https://ftcpublic.commentworks.com/ftc/acoenforcementpolicy.

AGENCIES OUTLINE FRAUD LAW WAIVERS

In connection with issuance of the CMS proposed ACO rule, CMS and HHS OIG issued a notice seeking comments on what kinds of health care fraud and abuse law waivers would be necessary for such health care entities. They jointly issued a notice with comment period outlining proposals for waivers of the physician self-referral law (known as the Stark law), the anti-kickback statute, and certain provisions of the civil monetary penalty (CMP) law in connection with the MSSP.

''My impression is that the anti-kickback statute and Stark waivers are minimal,'' Kevin McAnaney, an attorney with the Law Offices of Kevin G. McAnaney, Washington, told BNA April 4.

''No one in the industry really thought that the distribution of the Medicare bonuses were not going to be protected,'' he said. ''The issue is the investment in the infrastructure necessary for the ACO. On that issue, the waivers are no help.''

McAnaney did say that the proposed CMP waivers were a bright spot, as they would only prohibit payments that reduced or limited medically necessary care.

The shared savings program will reward the ACOs that reduce growth in health care costs while meeting performance standards on quality and ''putting patients first,'' CMS said in a fact sheet.

In the notice, the two agencies set forth proposals for waivers of the fraud and abuse laws ''that we believe, based on public input and our own analysis, may be necessary to carry out the Medicare Shared Savings Program.''

The agencies asked for public comment on the proposed waivers. In addition, the agencies asked for public input ''on the possibility of additional or different waivers, as well as input on other related considerations.''

''The waivers proposed by CMS and the OIG are quite flexible with regard to how an ACO could distribute shared savings received from CMS. In fact, certain stakeholders might consider the waivers too flexible in this regard,'' Daniel H. Melvin, an attorney with McDermott Will & Emery LLP in Chicago, told BNA April 4.

''With regard to funding of an ACO's infrastructure by a participating hospital, the government punted on whether waivers are needed to address the potential for such funding to create a financial relationship between the hospital and the ACO physicians who have not contributed to such funding. I expect that CMS and the OIG will receive a lot of comments on this issue,'' Melvin said.

Melvin said that the OIG/CMS notice also did not cover whether to extend waivers to distributions to ACO-participating physicians of shared savings or other pay-for-performance payments received by an ACO from private payers.

''CMS will receive a lot of comments on this issue as well,'' he said.

Working With ACOs. The agencies said they ''seek to address application of . . . fraud and abuse laws to accountable care organizations . . . so that the laws do not unduly impede development of beneficial ACOs, while also ensuring that ACO arrangements are not misused for fraudulent or abusive purposes that harm patients or Federal health care programs.''

In the OIG-CMS notice, *Medicare Program; Waiver Designs in Connection with the Medicare Shared Savings Program and the Innovation Center*, the agencies said the physician self-referral law, the anti-kickback statute, and the civil monetary penalty provision addressing hospital payments to physicians to reduce or limit services ''are important tools to protect patients and the Federal health care programs from fraud, improper referral payments, unnecessary utilization, underutilization, and other harms.''

The notice said that, ''However, stakeholders have expressed concern that the restrictions these laws place on certain financial arrangements . . . may impede development of some of the innovative integrated-care models envisioned by the Medicare Shared Savings Program.''

The agencies noted that Section 1899(f) of the Social Security Act [added by the health reform law in 2010] authorizes the secretary of health and human services to waive these and certain other laws as necessary to carry out the Medicare Shared Savings Program.

However, the agencies said that the waiver authority does not address other integrated delivery models, adding that they may consider waivers, exceptions, or safe harbors, as applicable, for other types of ACOs, integrated care delivery models, or financial arrangements at a later date.

Waiving Fraud Laws. The CMS fact sheet said the agencies' proposals would waive the fraud laws in three circumstances.

The first is the distribution of shared savings payments received by an ACO to or among qualified ACO participants and ACO providers/suppliers described in the notice with comment period.

The second is an ACO's distribution of shared savings payments to other individuals or entities for activities necessary for and directly related to the ACO's participation in the shared savings program.

Third, the anti-kickback statute and CMP would be waived for certain financial relationships that are ''necessary for and directly related to the ACO's participation in the Shared Savings Program and fully comply with an exception to the physician self-referral law.''

The agencies said these waivers ''would cover shared savings earned during the agreement period with CMS and, as applicable, financial relationships existing during the agreement period.''

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The agencies also listed several other waiver-related topics and asked for comments, including the use of the existing exception and safe harbor for electronic health record arrangements. The agencies also seek comments on whether final waivers should be published at the same time as the final rule on the ACOs from CMS.

Separate Waiver Authority. Finally, the agencies' notice also solicits comments on the best way to exercise the separate waiver authority under Section 1115A of the Social Security Act, which applies to the Innovation Center at CMS.

The OIG-CMS notice on waivers and the proposed ACO rule are scheduled for publication in the April 7 *Federal Register*. There is a 60-day comment period on the waivers notice.

In a statement, Blair Childs, senior vice president of public affairs for the Premier health care alliance, said that legal barriers ''traditionally have prevented innovative care delivery models from taking root.''

Childs added, ''We believe CMS's decision to grant waivers for the division of shared savings bonuses and a 'safe harbor' for other payments provides a greater level of legal assurance, and will allow a variety of ACO models to be tested over time, both in the Medicare program and among private payors.'' Premier is a health care group purchasing organization.

Comments should refer to file code CMS-1345-NC2, and should be sent to http://www.regulations.gov.

TAX-EXEMPT ORGANIZATIONS AND ACOS

Finally, the IRS guidance on the tax treatment of ACOs, and the exempt organizations that help form them, said nonprofit health care providers should be able to participate in the MSSP as long as they follow established guidance on the charitable nature exempt health care organizations must exhibit and the private inurement and benefit scenarios they must avoid.

IRS specifically said that exempt hospital participation in ACOs that are blessed by CMS will most likely qualify for continued exemption under federal tax laws because they will be entities that ''lessen the burdens of government'' by promoting health care quality improvements and cost savings for the Medicare program.

''Because of CMS regulation and oversight of the MSSP, as a general matter, the IRS expects that it will not consider a tax-exempt organization's participation in the MSSP through an ACO to result in inurement or impermissible private benefit to the private party ACO participants,'' the notice said.

To the extent participation in an ACO may generate MSSP revenues for an exempt organization, that revenue also should not be considered unrelated business income subject to tax as long as there is no private inurement or excessive private benefit, IRS said.

''The IRS expects that, absent inurement or impermissible private benefit, any MSSP payments received by a tax-exempt organization from an ACO would derive from activities that are substantially related to the performance of the charitable purpose of lessening the burdens of government within the meaning of Treas. Reg. § 1.501(c)(3)-1(d)(2), as long as the ACO meets all of the eligibility requirements established by CMS for participation in the MSSP,'' IRS said.

IRS took a more cautious stance with respect to revenues that might be generated from private insurer contracts by an ACO that has a tax-exempt participant. It suggested in the notice that interested parties should submit comments on the circumstances under which participation of an exempt organization in an ACO outside MSSP can be justified given the lack of CMS oversight and monitoring.

The notice did not shed any light on one recurring question that practitioners have raised since the ACO concept first surfaced: whether an ACO as a whole might be structured as an exempt organization.

Comments are due May 31.

Reaction. ''Basically the IRS guidance can be summed up in one word: punt,'' Matthew Amodeo, a partner with Drinker Biddle in Albany, N.Y., told BNA. ''The notice is a restatement of existing policy.''

However, the notice did flag two issues of concern to all exempt organizations contemplating participation in an ACO—avoiding private inurement and dealing with unrelated business income. In addition, the service held up ''lessening the burdens of government'' as the one of the main criteria for achieving the charitable purposes required for exempt status as ACOs.

The notice cited a litany of existing guidance on exemptions under tax code Section 501(c)(3), touching on a variety of factors that qualify as charitable purpose, such as relief of the poor and lessening the burdens of government.

The notice cited Revenue Ruling 98-15 and Rev. Rul. 69-545, which acknowledge the promotion of health as a charitable purpose. However, the IRS said that not every activity that promotes health supports tax exemption under tax code section 501(c)(3). For instance, selling prescription pharmaceuticals promotes health, but pharmacies cannot qualify for exemption on that basis alone, IRS noted.

Other guidance cited recognizes that the activities of limited liability companies treated as a partnership for federal income tax purposes are considered to be activities of a nonprofit organization that is an owner of the LLC when evaluating whether the nonprofit is operated exclusively for exempt purposes.

Private inurement will be the big issue going forward for ACOs, Amodeo said. ''ACOs must be primarily physician driven, and it's going to be very difficult to get tax-exempt status if the physicians are in control because it will raise questions of whether they are personally benefitting too much,'' he said.

The IRS pointed to the inurement question, saying ACOs must be structured so that they ensure that their participation in the shared savings program does not result in inurement.

An additional issue raised by the participation of tax-exempt organizations in ACOs is whether payments from the program will be subject to unrelated business income tax under tax code Section 511. That will depend on whether the activities generating the payments are related to the performance of its charitable purposes, IRS said.

Broad Look. The guidance indicates generally that the IRS is looking more broadly at ACOs, including commercial arrangements unrelated to Medicare, and whether participation in those ACOs raises exemption or ACO issues, said Gerry Griffith, a partner with Jones Day in Chicago.

It also notes that the Centers for Medicare & Medicaid Services' notice of proposed rulemaking would require including ACO participants or designees on the

ACO board and Medicare patients served by the ACO, but with no other financial connection to the ACO.

The notice, however, does not express any views on physician participation in governance and how that may affect the analysis either for Medicare or non-Medicare ACOs, Griffith said. It also indicates that the IRS is looking at ACOs structured as corporations, partnerships, and contractual arrangements. ''For all that promised breadth, however, this is still only a first step in the IRS guidance, albeit a positive one for what it does cover,'' he said.

Principles for Consideration. The IRS said that comments should take into consideration two principles under existing law. First, that although the promotion of health has been recognized as a charitable purpose, not every activity that promotes health supports tax-exemption under Section 501(c)(3).

Second, IRS said if a tax-exempt organization is a partner of an ACO treated as a partnership for federal tax purposes, the ACO activities will be attributed to the tax-exempt organization for purposes of determining both whether the organization operates exclusively for exempt purposes and whether it is engaged in an unrelated trade or business.

T.J. Sullivan, a partner with Drinker Biddle in Washington, said that on the one hand, he was a little surprised that the IRS went as far as it did to try to address key tax exemption questions. ''I'm guessing there was heavy pressure from 1600 Pennsylvania down through Treasury to say something both concrete and helpful,'' he said.

Perhaps most notable is that, for all IRS said about participation in ACOs in ways that would likely fit a joint venture definition, it seemingly forgot to mention the Rev. Rul. 98-15 control test. ''Whether this represents a substantive easing of the rules or is just an instance of the oft-recommended 'don't say anything if you can't say anything nice,' remains to be seen,'' he said.

Sullivan said, altogether, the notice is a very encouraging start, but, based on the narrowness of the specific safe harbor standards set out, and the huge variation in ACO structures and operations practitioners expect, IRS should be prepared for a huge volume of comments over the next 60 days.

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The CMS proposed rule is available at http://op.bna.com/hl.nsf/r?Open=bbrk-8fgkxb A fact sheet for providers put out by CMS is available at http://op.bna.com/hl.nsf/r?Open=nwel-8fgt5n A CMS fact sheet summarizing the proposed rule is available at http://op.bna.com/hl.nsf/r?Open=nwel-8fgt5e.

The FTC-DOJ statement on enforcement policy is at http://op.bna.com/hl.nsf/r?Open=psts-8fgren.

The IRS notice is available at http://op.bna.com/hl.nsf/r?Open=psts-8fgudy.

The CMS-OIG notice concerning fraud and abuse law waivers is available at http://op.bna.com/hl.nsf/r?Open=bbrk-8fgkyt. More information from the HHS OIG is available at http://oig.hhs.gov/fraud/aco.asp.

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