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CMS Sensitive or Controversial Questions and Answers Regarding the Medicare Shared Savings Program (Shared Savings Program) Notice of Proposed Rule Making (NPRM) Release March 31, 2011

What is an ACO?

Under the proposed rule, an ACO refers to a group of providers and suppliers of services (e.g., hospitals, physicians, and others involved in patient care) that will work together to coordinate care for the patients they serve with Original Medicare. The goal of an ACO is to deliver seamless, high quality care for Medicare beneficiaries, instead of the fragmented care that has so often been part of fee-for-service health care. The ACO would be a patient-centered organization where the patient and providers are true partners in care decisions.

The Affordable Care Act specifies that an ACO may include the following types of groups of providers and suppliers of Medicare-covered services:

- ACO professionals (i.e., physicians and hospitals meeting the statutory definition) in group practice arrangements,
- Networks of individual practices of ACO professionals,
- Partnerships or joint ventures arrangements between hospitals and ACO professionals, or
- Hospitals employing ACO professionals.
- Other Medicare providers and suppliers as determined by the Secretary

In the proposed rule, the Secretary has made clear that certain critical access hospitals are eligible to participate in the Shared Savings Program.

What do these rules mean for people with Medicare?

Any patient who has multiple doctors probably understands the frustration of fragmented and disconnected care: lost or unavailable medical charts, duplicated medical procedures, or having to share the same information over and over with different doctors. Accountable Care Organizations are designed to lift this burden from patients, while improving the partnership between patients and doctors in making health care decisions. People with Medicare will have better control over their health care, and their doctors can provide better care because they will have better information about their patients' medical history and can communicate with a patient's other doctors.

Medicare beneficiaries whose doctors participate in an ACO will still have a full choice of providers and can still choose to see doctors outside of the ACO. Patients choosing to receive care from providers participating in ACOs will have access to information about how well their doctors, hospitals, or other caregivers are meeting quality standards.

If You Like What You Have, You Can't Keep It

If a beneficiary's physician joins an ACO, that beneficiary must either become part of the ACO or find a new physician. The President has said "if you like what you have, you can keep it." This doesn't seem to be the case in the ACO rule. Why is the President forcing beneficiaries who want to keep what they have to change physicians?

Patient and provider participation in an ACO is purely voluntary. Patients in an ACO maintain complete freedom of choice to select their Medicare providers. We have proposed that providers participating in an ACO notify the beneficiary that the provider participates in an ACO. The beneficiary may then choose to receive services from that provider or seek care from another provider that is not part of the ACO.

Improving coordination and communication among physicians and other providers and suppliers will help improve the care Medicare beneficiaries receive.

Limiting Care for Beneficiaries / Sharing Risk

Your proposal would require all ACOs to bear risk – much like an HMO or managed care organization. Isn't the easiest way for an at-risk ACO to make a profit or to avoid having to repay money to CMS by limiting beneficiaries' access to care? How do you propose to monitor and prevent an ACO from limiting care?

ACOs that skimp on care will not qualify for bonuses. Under the proposed rules, to share in savings, ACOs would meet quality standards in five key areas:

- Patient/caregiver experience of care
- Care coordination
- Patient safety
- Preventive health
- At-risk population/frail elderly health.

The proposed rules also include strong protections to ensure patients do not have their care choices limited by an ACO. CMS has proposed a vigorous monitoring plan that includes analyzing claims and specific financial and quality data. We plan to generate quarterly and annual aggregated reports, visit some ACOs on site, and perform beneficiary surveys to make sure that ACOs are not stinting on care and are not avoiding at risk beneficiaries.

The Affordable Care Act contemplated a "Shared Savings Program" where ACOs would not have to accept risk. Yet your proposal requires that all ACOs accept risk either from the beginning or in the third year of their 3-year agreement. Haven't you essentially rewritten the law without involving Congress?

No, we propose to intensify the incentive for shared savings as outlined in the Affordable Care Act, making the policy more likely to meet the goals laid out in the law. In fact, Congress's own advisory group, the Medicare Payment Advisory Commission (MedPAC) has said that it believes offering a two-sided risk model is necessary for the program to meet its potential. MedPAC believes the two-sided risk model would increase the strength of the incentives to control spending and volume.

That said, the rule is in proposed form and we are interested in hearing public and stakeholder views on this and other parts of the proposal.

Data Sharing

The rule proposes to share beneficiary-identifiable data with an ACO. Does the beneficiary get to opt-out of or opt-in to the data sharing?

Beneficiaries' data will not be shared if they don't want it to be shared. Beneficiaries will be given information in writing about sharing personal health data the first time that they see an ACO provider. At that time, they will be offered the opportunity to opt out of having their Medicare claims data shared with the ACO. Under the proposal, the ACO would only be able to request data for beneficiaries who have visited a primary care provider and who have not chosen to opt-out of data sharing.

How do the privacy laws allow you to share data on a beneficiary's use of services by non-ACO providers with the ACO?

The HIPAA Privacy Rule permits CMS to share beneficiary identifiable data with ACO providers for the purpose of treatment and operations. ACO providers are only allowed to use the data for legally permissible purposes, according to the HIPAA Privacy Rule. The proposal takes the extra step of giving beneficiaries to option of preventing this permissible sharing of data.

What type of data is CMS providing to ACOs?

One important barrier to improving care coordination is that doctors often lack full information about the medical care their patients are or have received. In our discussions around the country with providers on this topic, we heard that while providers may know about the services they provide to the beneficiary, they don't know about other services provided to the beneficiary. CMS will provide doctors with the whole picture of medical services their patients are receiving. Part A and B data elements may include: beneficiary ID, date of birth, gender, procedure codes, diagnosis codes, dates of service, provider/supplier ID, and claim payment type. Part D data elements may include beneficiary ID, prescriber ID, drug service date, drug product service ID, and formulary identifier. This will help reduce duplicating care for patients – subjecting them to multiple unnecessary tests – as well as reduce adverse events.

Physician vs. Hospital and Specialists ACOs

Given the risk-bearing emphasis in the rule, it seems likely that only hospitals would be able to meet all your requirements. Isn't your proposal just going to force doctors to give up their practices and become employees of the hospital?

No. The goal of the program is to encourage care coordination between all providers, including physicians and hospitals. We think ACOs will develop in various innovative ways, according to the unique needs of each community. Some ACOs will be networks of physician group practices, others will be partnerships or joint ventures between hospitals and physicians, and others will create innovative models to achieve the goals of the program.

The proposal includes options and incentives for physicians to other types of providers to form and join ACOs. For example, there is an option for one-sided risk that will allow physician-based ACOs time to ramp up to bearing down-side risk. And, small ACOs in rural and underserved communities are exempt from the extra 2 percent minimum savings threshold, allowing them to get savings sooner than other types of ACOs.

We are interested in obtaining comments on the proposed rule on the kinds of ACOs that will form. We want to ensure a robust and varied field of providers, not a one-size fits all model, and seek approaches that will facilitate the development of a varied field.

How are networks of physician practices, particularly small physician practices in rural areas with limited resources, will be able to quality and function as ACOs? How many rural ACOs do you expect could meet all your onerous requirements?

Improving care for patients in rural areas is critically important. The Affordable Care Act included a number of provisions to assist rural providers, and the Medicare Shared Savings Program provides flexibility to organizations to determine the best structure to form an ACO.

We expect ACOs to form in rural areas as networks of physician group practices work together to coordinate care. We have proposed that certain critical access hospitals are eligible to participate as an ACO which should encourage ACOs to form in rural areas. We think rural providers will work together to creatively leverage resources to meet the requirements of the program. And, small ACOs in rural and underserved communities are exempt from the extra 2 percent minimum savings threshold, allowing them to get savings sooner than other types of ACOs.

We do not believe that the rule will disadvantage one group of providers over another, but look forward to hearing comments from the community on this issue.

There is a higher "minimum savings threshold" before shared savings can be received for small versus large ACOs. Isn't this an obvious bias against the creation and inclusion of small ACOs?

The reason to have a threshold in the first place is that there is often annual fluctuation in health spending that has nothing to do with the performance of health care providers – and the smaller the group of providers for which you are tracking spending, the greater that fluctuation. The minimum savings threshold is designed to ensure that shared savings result from performance, not from such fluctuations. That is why it is higher for small ACOs (3.9 percent) and lower for

large ACOs (2 percent). That said, we welcome comments on this and other provisions of the proposed regulation.

Why not let specialists rather than primary care doctors determine how beneficiaries are assigned to ACOs? Specialists are often the primary care providers for seniors.

This proposed rule, and the Medicare program in general, recognize the importance of primary care, no matter who delivers it. For example, the performance measures that determine how much of the shared savings an ACO gets are blind to which ACO provider or supplier delivers it. That said, the Affordable Care Act identifies certain types of physicians as primary care providers, and that definition is used in this rule. We look forward to hearing comments on whether this approach best achieves the goals of the Medicare Shared Savings Program.

Onerous Requirements

The proposed rule includes a number of onerous requirements prescribing how ACOs must be structured, including governance structure, program integrity requirements, use of savings, and 12 prescriptive patient centeredness criteria. Won't this limit flexibility for that ACOs need to innovate in the market?

The proposed rules do not impose requirements beyond those often required for other organizations responsible for Medicare beneficiary health, such as hospitals, managed care organizations or others. CMS has proposed certain criteria in order to make sure that ACOs are real organizations that are prepared to accept accountability for beneficiary health.

From experience with Medicare Advantage plans and Medicare prescription drug plans, CMS has learned the importance of setting requirements at the start of the program that set an organization on a path to compliance in order to protect beneficiaries.

This proposal strikes the appropriate balance between setting reasonable requirements to protect beneficiaries and allowing the industry the flexibility to innovate. We look forward to hearing from the provider community how best to ensure integrity of the program, and care improvements, through this new proposed regulation.

Isn't the requirement that at least 50 percent of participants must be using EHRs a backdoor way to screen out rural providers and physicians in small group practices?

No – it is designed to ensure that the ACO providers and suppliers have the means of communicating with each other, coordinating care, and minimizing the new reporting requirements since many of the quality measures used in the Shared Savings Program are also measures for "meaningful use" for electronic health records (EHRs). That said, we welcome comments on this and other provisions of the proposed regulation.

Reevaluation of ACO Applications

The proposed rule indicates that CMS plans to reevaluate an ACO's application every time the ACO changes a business process or when a provider joins or leaves the ACO.

What's the rationale for this level of Federal oversight? How quickly is CMS going to make these decisions?

We believe our proposal strikes the appropriate balance between setting reasonable requirements to protect beneficiaries and allowing the industry the flexibility to innovate.

As with other industries, significant changes in ownership trigger review to ensure the entity continues to meet standards that protect both patients and taxpayers. That is why we have proposed review of certain changes to the ACO's processes that are different from the ACO's initial application. The Agency will extend its customer focus to ensure organizations receive timely response.

Waivers

On October 5th, CMS hosted an all day conference to solicit input from the industry about items in the law that might need to be waived. The provider community offered numerous suggestions for needed flexibilities. Yet, in the proposed rule, CMS is only proposing to waive payment of shared savings. Why didn't the Agency incorporate other suggestions into the rule?

A: Existing rules designed to limit fraud and "kick-backs" that result from provider referring patients to each other were often designed before organizations like ACOs were on the horizon. We received helpful public comment from the October 5 meeting and also in response to the November 17 Request for Information Regarding Accountable Care Organizations and the Shared Savings Program. We used those comments in the development of our proposed rule and the waiver notice with comment period.

The rule seeks public input on the possibility of additional or different waivers, as well as any additional safeguards that might be necessary to protect beneficiaries and the Federal health care programs. We will consider all comments that we receive in response to our proposal as we finalize the rule.

Changing the Rules in the Middle of the Game

It appears that the proposed rule would allow CMS to change the rules of an ACO agreement after the ACO signs such an agreement with CMS. What is the rationale for changing the rules on providers in mid-stream?

The fundamental aspects of the ACO rules won't change, after they become final. For example, we do not anticipate that eligibility requirements relating to the structure and governance of the ACO; calculation of sharing rate; and beneficiary assignment.

However, other aspects of the program may change as CMS works with participating ACOs and beneficiaries to learn what is and is not working. Those potential program modifications, which may include quality measures, routine program integrity requirements, processes for quality management and patient engagement, and patient centeredness criteria, are unlikely to affect the

ACO's underlying organizational structure or its continued eligibility to participate in the program.

The Financial Benchmark

The statute describes a straight-forward way to calculate the benchmark based on historical costs of beneficiaries actually assigned. The rule proposes a complicated benchmark that isn't based on beneficiaries actually assigned to the ACO. Why did this change, and isn't this unfair to providers by not taking into account their specific patients?

The benchmark is the standard to which an ACO's performance is compared. It should represent the best estimate of what would otherwise happen in the absence of the ACO. We believe that establishing the benchmark based on average beneficiary expenditures adjusted for demographic characteristics would result in the best estimate of the ACO's performance. That said, we welcome comments on this and other provisions of the proposed regulation.

Why only share 50 to 60 percent of the savings that an ACO achieves with the ACO? Is that fair?

Today, Medicare gets all of the savings when providers reduce unnecessary care – under the Program and proposed rules, ACOs get a significant share of the savings. We think that this strikes the right balance, but welcome comments on it and other provisions of the proposal.

Windfall Bonuses

Your financial benchmark is increased by the absolute amount of growth in per capita Medicare fee-for-service expenditures. Won't this provide windfall bonuses to areas that are already efficient?

The statute requires that the financial benchmark be updated by the absolute amount of growth in per capita fee-for-service Part A and B spending. This helps prevent spending in the program from exceeding overall Medicare spending growth.

Withhold of Shared Savings

The proposed rule would withhold 25 percent of an ACO's shared savings performance payment to make sure the ACO is able to pay back any losses. How do you expect an ACO to incur the expenses to implement effective care coordination interventions if legitimately earned shared savings incentive payments are withheld?

The proposed rule balances the need to create reasonable incentives to help providers invest in improving care coordination, and the need to protect the Medicare Trust Funds. We believe our proposal is a reasonable approach to make sure the ACOs are able to pay Medicare for any losses without creating an undue burden on providers. That said, we welcome comments on this and other provisions of the proposed regulation.

Quality

The proposed rule includes 65 quality measures to assess the quality of care furnished by an ACO. However, the rule does not actually propose the specifics for certain measures or establish the performance standards until after the period ends.

How can an ACO take steps to improve quality if the organization does not know the quality requirements until after the fact?

As a reminder, in 2012, participating ACOs must report on these measures, but will not have their shared savings affected by their performance on the standards. We think our proposed quality measures give potential ACOs the information they need to decide whether they should participate in the program. Many of the quality measures are measures endorsed by the National Quality Forum and will be familiar to most ACOs. We expect to provide more details on the quality measures in sub-regulatory guidance.

Cost Shifting

Won't ACOs just shift their costs to other payers, leading to an increase in the overall health care costs?

A number of safeguards are built in to ensure that ACOs produce savings to the system. For example, the performance standards that ACOs must meet require them to develop processes and interventions to improve care coordination for Medicare patients. Yet, ACOs will likely apply those interventions to all patients, not just those assigned according to this program. This will lead to system-wide savings. We also propose to stop participation of ACOs that are avoiding at-risk patients as way to save money. We will monitor spending closely and calibrate the Program policies to ensure that it is a win-win: better quality for patients and lower spending for the health care system.

60-Day Comment Period

The proposed rule makes significant changes to the health care system and involves 4 major Departments of the government – yet it only gives the public 60 days to comment. Why are you only giving the public 60 days to analyze your proposal and submit comments?

60 days is the typical time provided for the public to comment on CMS proposed rules. The four agencies have held numerous meetings and calls on key issues on the program, and have conducted varying stakeholder sessions across the country over the past year to seek input from interested parties. Our work in engaging the public and soliciting comment and ideas has been ongoing for more than 12 months. HHS also announced it will hold a series of open-door forums and listening sessions during the comment period to help the public understand what CMS is proposing to do and to ensure that the public understands how to participate in the formal comment process

Innovation Center ACOs

How is this proposal different from what the Innovation Center will test for ACOs? When will your Innovation Center ACO proposal be released?

A: The Center for Medicare and Medicaid Innovation is charged by the Affordable Care Act to test innovative care and service delivery models. CMS is currently exploring how the Innovation Center will test alternative payment models for Accountable Care Organizations (ACOs). Once the Innovation Center releases a proposal, we will be able to provide additional information comparing the Medicare Shared Savings Program and the testing of new delivery models by the Innovation Center.

ACOs Based on Failed PGP Demo

The proposed ACO model is based on the Physician Group Practice (PGP) demonstration. A recent article in the New England Journal of Medicine (NEJM) pointed out the PGP demo was largely unsuccessful for most organizations in achieving shared savings. The NEJM article estimated that most of the PGP demo sites did not recoup their investments over a 3-year period. Since those PGP sites were large organizations that had the best chances for success, why do you think ACOs would be successful under your proposal?

A: While many design parameters are similar to the PGP demo, there are some design differences in the proposed rule. We have received significant interest in the proposed model and we believe many organizations are eager to innovate and make the investments necessary to change the delivery system. We also believe ACOs may see cost savings from improved efficiency, in addition to receiving shared savings that would help the ACO recoup the upfront infrastructure investment.

Won't some ACOs become a monopoly and drive up costs while limiting access to care? Need CMS to insert answer.