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Proposed federal rules on Accountable Care Organizations (ACOs)

The joke going around is that "ACO" really stands for "Abundant Consulting Opportunities" for attorneys and practice management experts. A nationwide scramble to make sense of ACOs was touched off on March 31. That was the day five federal agencies – the Centers for Medicare & Medicaid Services (CMS), the Inspector General, the Department of Justice, the Federal Trade Commission and the Internal Revenue Service – all released their coordinated proposals for how Accountable Care Organizations will be implemented, supposedly starting as early as January 1, 2012.

A sixty-day public comment period opened on April 7 and will run through June 6. The agencies will then draft final regulations for ACOs, a process that could take months and result in ACOs that look substantially different from what is currently proposed.

The Rhode Island Medical Society provided its members with a free two-hour introduction to ACOs and COOPs (Consumer Operated and Oriented Plans) on April 14. The seminar attracted 89 registrants and featured three experts on the still-emerging ACO and COOP models: Henry Allen, Esq., Senior Attorney for Advocacy with the AMA; Elias Matsakis, Esq., partner in the Chicago law firm Holland & Knight; and RIMS' own general counsel, Jeffrey F. Chase-Lubitz, Esq., of Donoghue, Barrett & Singal (Providence office).

The AMA offers all physicians a rich and growing online library of resources on ACOs and COOPs at <http://www.ama-assn.org/go/aco> under the title *Manual for Physicians Navigating a Post-Health Reform World*.

AMA, RIMS and other national and state medical societies continue to analyze the

proposals and will cooperate in providing feedback to the federal agencies by the June 6 deadline.

In addition, RIMS has been meeting with its counterparts in Connecticut, Massachusetts, New Jersey, New York and Pennsylvania and with AMA representatives to explore possibilities for regional collaboration. The medical societies want to help doctors seize whatever opportunities ACOs, COOPs and MEWAs (Multi-Employer Welfare Arrangements) may present to boost physician leadership and influence in the changing landscape of health care.

The year-old federal health care reform law and the new first draft of regulations envision ACOs as voluntary groupings or networks of

independent doctors and/or large medical practices, potentially in partnership with hospitals, federally qualified health centers, suppliers and even commercial health insurance plans. By working together to coordinate care, the ACO participants are supposed to share in the money they save for Medicare, while maintaining quality.

In order to be certified as an ACO and thus become eligible to share in the anticipated savings, the organization must include enough primary care physicians (defined by the proposed regulations as general internists, family physicians or geriatricians) to care for a minimum of five thousand Medicare patients. Those primary care physicians must be exclusively committed to a single ACO. Medical and surgical subspecialists, hospitals, health centers, rural clinics or other potential ACO partners need not be exclusively committed to a single ACO.

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ACOs, continued

Additional basic requirements for federal recognition as an ACO include a governing board and a formal legal structure through which shared savings payments can be distributed to the ACO's professional and institutional participants. An ACO must also be able to provide regular reports to CMS and to the public regarding participants, governance, quality and expenses; and it must commit

Gain-sharing will be contingent upon good scores on 65 quality measures.

to participating in Medicare as an ACO for at least three years at a time.

ACOs were conceived to provide a unique opportunity for physicians to take the initiative in creating and being the leaders of new models for integrated health care delivery.

The government's prime objective with the ACO program, of course, is to save money for Medicare while maintaining the quality of patient

care. However, it is clearly not the expectation of federal policy-makers that ACOs will become the dominant model for delivering and paying for health care, at least not any time soon. CMS is saying that it expects only 75 to 140 or so ACOs nationwide to begin operations next year.

In essence, then, ACOs are another experimental step in the government's search for structures and formulas that simultaneously control cost and promote quality.

Will they fly?

Some observers question the economic viability of ACOs and doubt that they will attract many participants at all. Some already dismiss the ACO idea as old wine in new bottles – or worse, as potentially costly dead-ends for doctors who venture into them.

Naturally, the answers come down to dollars and cents. Are the numbers realistic? Are they sufficient to have the desired impact on cost and quality in the long term?

CMS proposes to pay physicians in ACOs under the familiar Medicare Part B fee-for-service schedule. To establish annual benchmarks for ACOs, CMS will look back at six months' past claims experience of the Medicare population that CMS attributes to the ACO (a problematic process in itself: see below), aggregate it, and convert it to a per-beneficiary benchmark as a spending target for the coming year.

Providence attorney Don E. Wineberg of the firm Chace Ruttenberg and Freedman suggests some simple calculations to get a rough idea of the possibilities. Nationwide, Medicare's average actual expense per beneficiary in 2009 was \$10,400. Taking that number as a hypothetical ACO capitation benchmark and assuming that the ACO a) chooses to optimize its gain-sharing by accepting downside risk from day one and b) is very successful in achieving both high efficiency and high quality, then the

ACO would earn the maximum return, which is capped at 10% of its benchmark. That would amount to \$1040 per beneficiary or \$5.2 million for an ACO that has the minimum enrollment of 5000 Medicare beneficiaries.

Alternatively, if that same successful ACO more cautiously participates only in upside gain-sharing in the first two years, its maximum return would be \$780 per Medicare beneficiary or \$3.9 million per year.

Would such numbers be sufficient to stimulate and sustain ACOs, given the necessity of sharing among the ACO participants and bearing in mind that gain-sharing will be contingent and prorated, based upon the ACO's success in demonstrating sufficient quality in five "domains" involving 65 quality measures?

Moreover, ACOs are likely to have start-up costs that will need to be amortized. The ten ACO pilots, which started in 2005 in various parts of the country, incurred start-up costs of \$1.76 million on average. (And, by the way, when all was said and done, most of those ten pilots actually earned little or nothing in shared savings between 2005 and 2009.)

One additional caveat: CMS plans to withhold 25% of shared savings as a hedge against future losses that the ACO might incur and be required to share in as well.

Another sample calculation

RIMS' legal Counsel Jeffrey F. Chase-Lubitz took a different approach in gauging how an ACO might work (or not work) for physicians. In Providence County, Medicare spent an average of \$9,024 per Medicare beneficiary (fee-for-service) in 2008. Multiplying that number by the ACO minimum of 5000 Medicare beneficiaries yields a total potential benchmark budget of \$45,120,000 within which the ACO would have to provide the full spectrum of care to those beneficiaries for one year.

Assuming that the ACO succeeded in reducing hospital admissions by fully 10% in that year (from about 1600 to about 1440 in Providence County) and assuming further that each such admission is worth about \$12,800 to Medicare, then the ACO would realize savings of \$2,048,000 or 4.54% of its benchmark. For a small ACO that opted cautiously for upside sharing only with no downside risk, Medicare would claim the first 3.9% of the benchmark (\$1,759,680), leaving just \$288,320 available for sharing. Between zero and 50% of that amount (i.e., up to \$144,160, depending on the ACO's success in returning good quality measures) could be returned to the ACO to amortize its start-up costs and distribute among its participants. Medicare would keep the remainder.

Alternatively, a small ACO could opt to place itself at down-side risk from the start and thereby reduce

How achievable are the benchmarks set by CMS likely to be?

the initial threshold for sharing from 3.9% to 2%, producing \$1,145,600 available for sharing under the above scenario. How much of that \$1,145,600 would actually be returned to the ACO in shared savings could vary from zero up to a maximum of 60% (\$687,360), depending again upon the ACOs simultaneous success in meeting 65 measures across five “domains” of quality. (See “Quality reporting” below.)

Again, a further caveat is that CMS will impose a 25% withhold, which will reduce the flow of shared savings.

Surprise: ACOs will share in losses as well as savings

Under Section 3022 of the year-old federal health care reform law, the formation of ACOs is incentivized by the promise that ACO participants will share in the eventual savings to Medicare.

But when the new regulatory proposal came out at the end of March, it included downside risk as well as upside rewards.

Sharing of both savings and losses would kick in only when there is a difference, whether positive or negative, of at least

2% between the benchmark and the actual experience for the calendar year. The smallest ACOs (those closer to the minimum of 5000 Medicare patients) would have to better their benchmark by almost twice as much – 3.9% – in order to trigger shared savings. After the minimum differentials are reached or exceeded, ACO and CMS will roughly split the difference retroactively, up to a capped proportion in relation to the original benchmark. The cap would vary between 7.5% and 10% of the benchmark, with the higher percentage reserved for ACOs that are also exposed to downside risk.

ACOs can choose to be at risk for losses from the start or to postpone downside risk until the third year of their operation; however, by the third year and in all subsequent three-year agreements, all ACOs will be “accountable” for downside risk as well as upside savings, according to the proposed regulations.

The shared loss arrangement would roughly mirror shared savings. That is, if losses amount to at least 2% of the benchmark, CMS and the ACO would split the negative difference roughly in half, up to a cap of 5% of the benchmark for a fully at-risk ACO in the first year, up to 7.5% in the second year, and up to 10% in the third. For those ACOs that opt to postpone risk-sharing until the third year, a loss cap of 5% would be applied only in that last year.

The proposed ACO regulations foresee a sliding scale of thresholds for gain-sharing, ranging between 2% and 3.9%, depending upon the size of the ACO. Citing the experience of the ten government ACO pilot programs during 2005–2009, the American Medical Group

Association estimates that the proposed 2% threshold for shared savings will be a challenge for ACOs to achieve and that the 3.9% threshold foreseen for the smallest ACOs will be “very difficult.”

Quality reporting

Even if an ACO succeeds in substantially improving upon its spending benchmark, actually sharing in any of the realized savings is contingent upon, and proportional to, good scores on sixty-five quality measures distributed across five “domains” of patient care. Each domain is weighted equally in a point system that totals 130 points (two points for each of the 65 measures).

The five domains are: patient experience; care coordination; patient safety; preventive health; and at-risk/frail elderly health. The measures and the domains may expand in the future to include things like hospice care and nursing home measures.

A closer look at the five domains offers some clues to the government’s thinking and betting. The domain of “care coordination,” for example, includes a subcategory called “management of ambulatory sensitive conditions.” It turns out that these “conditions” include the following seven disease categories: diabetes with short-term complications; diabetes with long-term complications; COPD; heart failure; dehydration; pneumonia; and urinary tract infection. The quality measures for these seven conditions account for 14 out of the total 130 quality points.

Where will the savings come from?

CMS believes that the number of hospital admissions and readmissions for these “ambulatory sensitive conditions” are an index to how well the outpatient primary care system is functioning. CMS further assumes that managing those same “ambulatory sensitive conditions” is a key to significant savings through lower rates of hospital admission and readmission.

For those contemplating the formation of an ACO, it might appear that partnering with a hospital might invite internal disharmonies, since shared savings would be unlikely to fully offset the financial consequences of a lower inpatient census for the institution.

CMS will control the benchmarks and quality measures

Every ACO will be assigned its own new benchmark annually, based on recent claims experience for the ACO’s retroactively assigned Medicare patient population and adjusted in light of nationwide spending trends. How reasonable, challenging or achievable are the benchmarks set by CMS likely to be? The answer may vary from

**Antitrust
enforcement
is not
going away.**

**ACOs forming now
need to anticipate
changes in Medi-
care’s payment
structure.**

year to year and from ACO to ACO. CMS plans to apply managed care's "hierarchical condition categories" risk-adjustment methodology to ACO populations.

Definition of "primary care physician"

The federal health care reform law and the proposed regulations call for each ACO to be built on a foundation of primary care physicians, who are defined as general internists, family physicians and geriatricians. This definition may be contested by other specialty groups who seek more direct inclusion in the ACO model. Already the Neuropathy Association and the American Academy of Neurology are promoting legislation in Congress (S. 597) which would amend the ACA's definition of "primary care physician" to include neurologists.

"Meaningful use" will be required of at least 50% of ACO primary care physicians by the ACO's second year of operation

This requirement may prove to be a barrier for some would-be ACOs, especially in underserved and rural areas of the country. Perhaps the final regulations will drop this requirement. After all, given the incentives that already exist under the HITECH Act for achieving "meaningful use" of electronic health records, the inclusion of an additional requirement under the ACO regulations may have little additional impact.

ACOs will not control their assigned population of beneficiaries

Patients will remain free to seek care wherever they like. CMS will automatically assign (and reassign) patients to ACOs, based retroactively on Medicare claims data that indicate where the patient has been seeking the greatest proportion of his or her care. Thus, snowbirds may present a challenge to the ACO model.

What about HIPAA?

The proposed data sharing and information technology provisions of the ACO regulations suggest that ACOs should be prepared to shoulder some extra burdens for HIPAA compliance. CMS proposes to provide ACOs not only with aggregated data on the Medicare population the ACO serves, but also, upon the ACO's request, individually identifiable beneficiary information. No doubt ACOs will need such information to improve care coordination and overcome inefficiencies. However, since ACO participants may include both "covered entities" and "business associates" in HIPAA parlance, ACOs will need to have all necessary "Business Associate Agreements" in place and otherwise be up to snuff with HIPAA.

What about antitrust?

In the past, independent medical practices and other competitors who cooperated in sharing information and resources without being financially and/or clinically integrated risked draconian anti-trust sanctions. Now, to encourage collaboration and coordination, the Justice Department and the Federal Trade Commission propose to amend their rules to define new safety zones for ACO participants.

However, antitrust enforcement against "non-competitive behavior" is not going away. Physicians will need to familiarize themselves with the new rules and make sure they get good legal advice.

ACO applicants will have to move quickly once the final ground rules are known.

What about Stark (self-referral) and anti-kickback laws?

Here again, the federal authorities propose to carve out safety zones to permit ACOs to function and engage in collaborative gain-sharing. The initial new proposals were published on March 31 and are currently open for public comment. ACO aspirants will have to follow these developments carefully and make sure to be in compliance.

What about future payment models?

The proposed regulations are predicated on fee-for-service Medicare, but clearly CMS is planning more bundled payments in the future, with more global fees for "episodes" of care. ACOs forming now need to anticipate changes coming soon in the payment structure used by Medicare and commercial payers.

Will CMS stick to the January 1, 2012, start date for ACOs?

Straws in the wind suggest the implementation schedule will slip. The public comment periods close on or before June 6, after which CMS and the other agencies may take months to digest the feedback and draft final regulations. ACO applicants will have to move quickly once the final ground rules are known. A secondary start date of July 1, 2012, was already foreseen in the proposed regulations and required a 3.5 year commitment rather than three years. Perhaps July 1, 2012, will, by default or by regulation, become the real start date for everyone.

How significant will the differences be between the proposed ACO regulations issued on March 31 and the final version that we will see at an unknown time later this year?

Changes may be highly significant for some ACO applicants and insignificant for others. Early movers may have an advantage, if they are reading the tea leaves and their own circumstances correctly. On the other hand, early movers may find themselves tripped up if the regulators change their ACO vision in unanticipated ways. ❖