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The Proposed ACO Program: Issues for the Life Sciences Industry

By Ian Spatz and Wendy Krasner

Accountable care organizations (ACOs), a creation of the controversial Accountable Care Act (ACA), are among the most discussed innovations in health care delivery. These organizations are groups of health care providers that agree with Medicare to be accountable for at least 5,000 Medicare fee-for-service beneficiaries in exchange for receiving Medicare payment incentives under the Centers for Medicare & Medicaid Services (CMS) ACO Shared Savings Program. While still little more than a concept, they have attracted the attention of hospitals, primary care physicians, specialists, and other health care providers. Now, life science companies are taking a long, hard look at ACOs to determine what effect they may have on sales of existing therapies and the incentives to create new ones.

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On April 7, CMS published its long-anticipated proposed regulations for the Medicare Shared Services Program (MSSP). While ACOs also may be created under state laws for commercial populations and Medicaid, the MSSP is seen as the best guide to how ACOs will be constructed and operated.

The proposed rule is quite detailed and complicated.[1] It provides some good clues as to how Medicare ACOs might affect the pharmaceutical and biotechnology industries. Although much will be learned once ACOs begin to form, there are three interrelated questions that ACOs are likely to raise for industry:

- what effect ACOs will have on the appropriate use of medicines in Medicare Parts A, B, and D;
- how and whether industry will be involved in the financing, governance, and operation of an ACO; and
- how the program's quality performance measures will influence the use of medicines.

Proposed Rule's Effect on Appropriate Use

Because the goal of the Medicare ACO program is to encourage the more effective and efficient use of health care resources through collaboration among providers, the MSSP should be expected to affect the utilization of all health care items and services, including medicines. MSSP financial incentives are structured to reward ACOs and their member providers for reducing the to-

[1] Rather than summarize these rules and the related agency issuances released at the same time, we have included at the end of this article citations to several excellent publicly available summaries and assessments of the proposed ACO program.

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tal health care costs of those Medicare beneficiaries assigned to the ACO compared to the experience of the entire Medicare population.

Therefore, some may see that ACOs have an incentive to reduce the use of pharmaceutical and biotechnology products, especially those that are high-cost. Of course, ACOs' likely effect on utilization is far more complex.

The vast majority of pharmaceutical and biotechnology medicine spending in Medicare is through Part D, the outpatient prescription drug benefit.[2] It could prove highly significant that in computing its cost benchmarks for the purpose of calculating ACO bonuses or risk payments, the MSSP does not include Medicare Part D drug spending. This implies that the promise of shared savings or the fear of required payments to Medicare for spending more than benchmarks will not be much of a disincentive to ACO-participating physicians prescribing outpatient medicine.

Looked at another way, it is possible that the financial incentives to reduce health costs could induce even greater use of outpatient medicines as ACO providers seek to substitute, wherever possible, Part D costs that are not ''counted against them'' for other Medicare costs for which they will be held accountable. This could come directly by seeking Part D alternatives for medicines that otherwise would be provided through Part B. It also could come indirectly in the prescribing of medicines that an ACO participant might believe would reduce the need for Part A or B services such as hospitalizations. This could suggest an ACO focus on preventive prescribing and on adherence.

In contrast to its effect on Part D utilization, the MSSP could primarily affect the use of Part B medicines while having a secondary effect on the use of medicines in hospitals through Part A.

In terms of Part B, there could be a legitimate concern that, because the proposal benchmarks performance against previous years, it may not adequately take into account the costs of new Part B medicines. This may be a special concern with certain new, high-cost therapies. An ACO seeking to restrict cost growth to earn MSSP bonus payments may seek to work with its participating physicians to discourage the use of new medicines. This could be facilitated by the required ACO elements of shared decisionmaking, linked communications, and common medical protocols.

Mitigating Factors

Two factors may eliminate or ameliorate such an outcome. First, ACO performance is measured relative to all Part A and B spending. Medicines are a small portion of total Part A and B spending and, therefore, providers will have much greater incentives to reduce the major cost drivers such as avoidable hospitalization and preventable rehospitalization.

Second, the MSSP operates as an overlay to the traditional Medicare fee-for-service program with its complicated payment schedules. In the case of medicines, providers have incentives to furnish them through Part B. These incentives may be far greater and of more immediate benefit to a provider than the possibility that his or her decision might influence a possible bonus payment down the road. This is representative of the entire challenge of ACOs. Will they create incentives to save money sufficient to overcome existing incentives to do more?

In the case of Medicare Part A, given that current payment formulas are oriented around the episode of care for a given hospital visit, it is unlikely that ACO incentives will have a distinct effect on the uptake of new medicines.

Finally, although Part D medicine use is not considered in computing ACO rewards, the proposed MSSP regulation ensures that ACOs will get access to the Medicare Part D data of beneficiaries assigned to the ACO (subject to the beneficiaries' right to opt out of having their data released). CMS expects that ACOs participating in the MSSP would use information on prescription drug use to ''improve the quality of care furnished to their assigned beneficiaries'' and ''enhance care coordination for these beneficiaries.''

As a result, CMS has proposed providing ACOs with the minimum Part D data necessary to: (a) permit the ACO to evaluate the performance of ACO participants and ACO providers/suppliers; (b) conduct quality assessment and improvement activities with and on behalf of the ACO participants and ACO providers/suppliers; and (c) conduct population-based activities relating to improved health for Medicare beneficiaries who have a primary care visit with a primary care physician used to assign patients to the ACO during a performance year.

Companies as ACO Participants

While the MSSP contemplates that the major impetus for ACO creation and governance will come from primary care physicians and their partners in providing health care, life science companies may possibly want to play a role. It is conceivable that this may come in the formation, governance, financing, and operation of an ACO. A company may want to relate to an ACO as an investor (ownership interest), financer (providing loans), contractor, or even participant. However, it is not clear from the proposed rule how and whether pharmaceutical and biotech companies (hereafter, ''companies'') can play such roles.

Under the proposal, an ACO participant is either a provider or a supplier. Companies are not providers but may be considered suppliers if they bill for items furnished to Medicare beneficiaries under a Medicare billing number. It is not clear that all companies would qualify under this definition. However, even if not a participant, a company may be able to be part of the governance structure, as the proposal provides that 75 percent of an ACO governing body must be made up of ACO participants. Thus, others may comprise the remaining 25 percent.

In terms of the composition of the ACO governing body, ACO participants also must have a ''meaningful commitment'' to the ACO, which could include a meaningful financial or human investment in the ongoing operations of the ACO. The rules further require a proportionate control of the ACO by the participants. It is not clear what this means, e.g., participation based on investment? If so, that could be a problem for any role for companies since ACOs may not want them because the amount they could invest may be very limited;

[2] According to a recent analysis from Avalere, the federal government spent $11 billion on brand-name drugs in 2010 through Medicare Part B compared to $36 billion through Part D. *See* http://www.avalerehealth.net/wm/show.php?c=1&id=880.

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moreover, the companies may not want to invest since any control would be limited to a proportionate part of the 25 percent. Regardless of the above limits, however, the proposed rule indicates that CMS retains the right to give consideration to an innovative ACO with a management structure not meeting the requirements.

Companies also may want to participate with ACOs by signing contracts with them. Such contracts might involve payments from the company to the ACO to sponsor disease management programs, adherence programs, or other non-product-specific programs that would improve the ACO's ability to provide quality care and meet the quality standards for ACOs (as determined below). It is possible that companies also may see such programs as indirectly beneficial to the use of their medicines.

In this regard and to the extent that a company may seek to contract with an ACO to specifically encourage the use of a medicine, the ACO and the company will need to pay careful attention to the existing Medicare rules that prohibit payments to induce the use of Medicare-covered products and services. Specifically, partnership and access opportunities would need to be evaluated with regard to the joint OIG/CMS notice referenced in the proposed rule. That notice provides that ''the provisions of any free services (telehealth, case managers, etc.) between parties in a position to generate Federal health care program referrals could trigger evaluation under the relevant fraud and abuse laws.'' Stakeholders interested in this issue also may wish to comment on the joint OIG/CMS notice.[3]

Company-Related Quality/Performance Measures

CMS has proposed a quality performance standard for determining an ACO's eligibility to participate in shared savings based on 65 quality measures in five domains. It is through these quality measures that MSSP ACOs may have some of their greatest effect on pharmaceutical and biotechnology product use.

In developing the quality score, the ACO will be evaluated for quality at three levels, including at the level of an individual measure, an aggregate of all measures within each domain, and a single performance score across all measures and domains. The latter will be applied to determine the quality sharing rate for which the ACO is eligible.

CMS views the ACO as an important part of its new three-part aim, defined as a new approach to the delivery of health care through (1) better care for individuals, (2) better health for populations, and (3) lower growth in expenditures. The shared savings approach is designed to reward providers for achieving the ''triple aim'' by developing the system-wide changes required to improve care for individuals and populations. Quality measures are at the core of the first two parts of the triple aim, and the 65 quality measures, listed in Table 1 of the proposed rule, reflect a mix of both individual-focused and population-based measures. The quality measures also reflect a range of process-of-care and health outcome measures, as well as several experience-of-care measures reported by patients.

Five Domains of the ACO Quality Performance Standard	
Better Care for Individuals	**Better Care for Populations**
1. Patient/caregiver experience	4. Preventive health
2. Care coordination	5. At-risk populations
3. Patient safety	

The proposed quality measures fit within five key domains related to ''better care'' for individuals and improved health for populations. ACOs are expected to focus on improving care in each of these five domains as a means of improving the overall quality of care provided to Medicare beneficiaries. Moreover, the underlying system-wide changes that are required to improve care are likely to affect all patients seen by the providers participating in the ACO. In fact, CMS is planning to develop a single quality measure set for ACOs serving individuals covered by other government programs, in addition to Medicare.

In the short term, an ACO may be focused on some quality measures where improvements are easier to achieve, regardless of their effect on overall spending. For example, the quality measures focused on preventive services, which could increase an ACO's costs, are a likely target for performance improvement because no major system issues are involved. Improvements in the preventive services quality metrics may be an important baseline contribution to the ACO's quality score. Additional short-term measures, such as those focused on care coordination, are also targets for improvement, although the needed system requirements make them more challenging to achieve. For these types of measures, ACOs may first focus on some specific improvements, such as a reduction in avoidable hospital readmissions and emergency-room visits for certain populations with chronic conditions. CMS expects that these targeted changes may be achieved within an ACO's initial three-year agreement. More importantly, CMS expects that an ACO's investments in care coordination systems and process improvements can be leveraged over time so that more comprehensive efficiency gains and quality improvements will be possible.

As shown in the table below, almost two-thirds of the proposed ACO quality measures could have a direct or indirect effect on the use of prescription drugs:

- Twelve measures could have a direct effect on drug utilization because the use of a specific type of drug or vaccine is being assessed by the measure, and
- Twenty-nine measures could have an indirect effect on drug utilization because of the availability of particular drug therapies to treat a clinical indication (high cholesterol) related to the quality measure, such as low density lipoprotein (LDL-C) control in diabetes mellitus.

[3] Medicare Program: Waiver Designs in Connection with the Medicare Shared Savings Program and Innovation Center, Office of the Inspector General, HHS; http://www.gpo.gov/fdsys/pkg/FR-2011-04-07/pdf/2011-7884.pdf.

Table 1: Proposed ACO Quality Measures*			
Proposed Quality Measure		Effect on Rx	
#	Name	Direct	Indirect
AIM: Better Care for Individuals			
1	■ **Clinician/Group CAHPS:**		
	✓ Getting Timely Care, Appointments, and Information		
2	✓ How Well Your Doctors Communicate		
3	✓ Helpful, Courteous, Respectful Office Staff		
4	✓ Patients' Rating of Doctor		
5	✓ Health Promotion and Education		
6	✓ Shared Decisionmaking		
7	■ **Medicare Advantage CAHPS:** ✓ Health Status/Functional Status		
8	■ **Risk-Standardized, All Condition Readmission**		
9	■ **30-Day Post Discharge Physician Visit**		
10	■ **Medication Reconciliation**		☒
11	■ **Care Transition Measure:**Uni-dimensional self-reported survey that measures the quality of preparation for care transitions. Namely: – Understanding one's self-care role in the post-hospital setting – Medication management – Having one's preferences incorporated into the care plan		☒
	■ **Ambulatory Sensitive Conditions: Admissions for —-**		
12	✓ Diabetes, short-term complications (AHRQ Prevention Quality Indicator (PQI) No. 1)		☒
13	✓ Uncontrolled Diabetes (AHRQ Prevention Quality Indicator (PQI) No. 14)		☒
14	✓ Chronic obstructive pulmonary disease (AHRQ Prevention Quality Indicator (PQI) No. 5)		☒
15	✓ Congestive Heart Failure (AHRQ Prevention Quality Indicator (PQI) No. 8)		☒
16	✓ Dehydration (AHRQ Prevention Quality Indicator (PQI) No. 10)		☒
17	✓ Bacterial pneumonia (AHRQ Prevention Quality Indicator (PQI) No. 11)		☒
18	✓ Urinary infections (AHRQ Prevention Quality Indicator (PQI) No. 12)		☒
19	■ **Percentage of Physicians Meeting Stage 1 HITECH Meaningful Use Requirements**		
20	■ **Percentage of PCPs Meeting Stage 1 HITECH Meaningful Use Requirements**		
21	■ **Percentage of PCPs Using Clinical Decision Support**		
22	■ **Percentage of PCPs who are Successful Electronic Prescribers Under the eRx Incentive Program**		
23	■ **Patient Registry Use**		
24	■ **Health Care Acquired Conditions:** ✓ Composite Measure		☒
25	■ **Health Care Acquired Conditions:** ✓ CLABSI Bundle		☒
AIM: Better Health for Population			
26	■ **Influenza Immunization** ✓ Percentage of patients age 50 years and older who received an influenza immunization during the flu season (September through February).	☒	
27	■ **Pneumococcal Vaccination** ✓ Percentage of patients aged 65 years and older who have ever received a pneumococcal vaccine.		
28	■ **Mammography Screening** ✓ Percentage of women age 40 through 69 years who had a mammogram to screen for breast cancer within 24 months.		
29	■ **Colorectal Cancer Screening** ✓ Percentage of patients age 50 through 75 years who received the appropriate colorectal cancer screening.		
30	■ **Cholesterol Management for Patients with Cardiovascular Conditions:** ■ LDL-C control (<100 mg/dL)		☒
31	■ **Adult Weight Screening and Follow Up**		
32	■ **Blood Pressure Measurement**		☒
33	■ **Tobacco Use Assessment and Tobacco Cessation Intervention**		☒
34	■ **Depression Screening**		☒

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Table 1: Proposed ACO Quality Measures*			
Proposed Quality Measure		Effect on Rx	
#	Name	Direct	Indirect
35	■ **30-Day Post Discharge Physician Visit**Diabetes composite (all or nothing scoring): ✓ Hemoglobin A1c Control (<8 percent) ✓ Low Density Lipoprotein (<100) ✓ Blood Pressure <140/90 ✓ Tobacco Non-Use ✓ Aspirin Use		☒
	■ **Diabetes Mellitus:**		
36	✓ Hemoglobin A1c Control (<8%)		☒
37	✓ Low Density Lipoprotein (LDL-C) Control in Diabetes Mellitus		☒
38	✓ Tobacco Non-Use: Tobacco use assessment and cessation		☒
39	✓ Aspirin Use: Daily aspirin use for patients with diabetes & cardiovascular disease	☒	
40	✓ Hemoglobin A1c Poor Control(>9%):		☒
41	✓ High Blood Pressure Control in Diabetes Mellitus		
42	✓ Urine Screening for Microalbumin or ✓ Medical Attention for Nephropathy in Diabetics.		☒
43	✓ Dilated Eye Exam in Diabetic Patients		☒
44	✓ Foot Exam		☒
	■ **Heart Failure:**		
45	✓ Left Ventricular Function (LVF) Assessment		
46	✓ Left Ventricular Function (LVF) Testing		
47	✓ Weight Measurement		
48	✓ Patient Education		
49	✓ Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD)	☒	
50	✓ Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD)	☒	
51	✓ Warfarin Therapy for Patients with Atrial Fibrillation	☒	
52	■ **Coronary Artery Disease (CAD)** ✓ Composite: All or Nothing Scoring – Oral Antiplatelet Therapy Prescribed for Patients with CAD – Drug Therapy for Lowering LDL-Cholesterol – Beta-Blocker Therapy for CAD Patients with Prior Myocardial Infarction (MI) “ – LDL Level <100 mg/dl – Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Patients with CAD and Diabetes and/or Left Ventricular Systolic Dysfunction (LVSD)	☒	
53	✓ Oral Antiplatelet Therapy Prescribed for Patients with CAD	☒	
54	✓ Drug Therapy for Lowering LDL-Cholesterol	☒	
55	✓ Beta-Blocker Therapy for CAD Patients with Prior Myocardial Infarction (MI)	☒	
56	✓ LDL level < 100 mg/dl		☒
57	✓ Angiotensin-Converting Enzyme (ACE) Inhibitor or ✓ Angiotensin Receptor Blocker (ARB) Therapy for Patients with CAD and Diabetes and/or Left Ventricular Systolic Dysfunction (LVSD)	☒	
	■ **Hypertension (HTN):**		
58	✓ Blood Pressure Control		☒
59	✓ Plan of Care		☒
	■ **Chronic Obstructive Pulmonary Disease (COPD):**		
60	✓ Spirometry Evaluation		☒
61	✓ Smoking Cessation Counseling Received		☒
62	✓ Bronchodilator Therapy based on FEV1	☒	
63	■ **Falls:** ✓ Screening for Fall Risk		
64	■ **Osteoporosis Management** ✓ in Women Who had a Fracture		☒
65	■ **Monthly INR for Beneficiaries on Warfarin**		☒

* Excerpted from Table 1 in notice of proposed rulemaking, Centers for Medicare & Medicaid Services, U.S. Department of Health and Human Services, Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations, 76 Fed. Reg. 19528 at 19571 (April 7, 2011). [Please note that column titled ‘‘Effect on Rx’’ was added by the authors.]

Two of the preventive measures could affect the utilization of vaccines, particularly influenza immunization and pneumococcal vaccination. Other measures could increase the use of drug therapies such as: angiotensin receptor blocker (ARB) therapy; beta-blocker therapy; angiotensin-converting enzyme (ACE) inhibitor therapy; bronchodilator therapy; oral antiplatelet therapy; and warfarin therapy.

These drug therapies are associated with disease-specific quality measures including diabetes mellitus, heart failure, coronary artery disease (CAD), and chronic obstructive pulmonary disease (COPD).

The 29 measures that could have an indirect effect on drug therapy utilization include a range of measures related to care coordination, preventive and screening services, and risk management strategies for at-risk population groups including those with diabetes, heart failure, CAD, COPD, and hypertension.

Care coordination measures such as those for medication management or hospital admissions related to ambulatory sensitive conditions could affect an array of drug therapies, particularly because the individuals who require care coordination are more likely to have multiple chronic conditions and require drug therapies across several classes.

In contrast, some of the preventive and screening measures could affect a particular class of drug therapies. For example,

- the depression screening measure could have an indirect effect on the use of a wide range of drug therapies used to treat depression,
- the blood pressure measures for some at-risk populations may increase the use of a wider range of drug therapies used to manage hypertension, and
- the screening and diagnostic measures for the diabetes at-risk population could increase the use of drug therapies beyond those listed in a specific measure found in other at-risk population group measures such as ACE inhibitor or ARB therapies that are referenced in measures for the heart failure and CAD populations.

While some stakeholders have expressed support for the proposed ACO quality measures, others have expressed doubt about the feasibility of the required data reporting or their adequacy in determining whether ACOs are achieving their intended goal. For example, the adequacy of the proposed measures was addressed by AdvaMed President and Chief Executive Officer Steve Ubl in a recent blog posting, who noted that the ACO quality measures ''do not generally measure outcomes and there are vast areas of clinical practice which are not addressed at all.''[4] In part, Ubl's concern reflects a finding in a recent Avalere report indicating that care transitions are uniquely addressed in only 5 percent of the 695 National Quality Forum-endorsed measures. Moreover, half of these 35 measures apply to multiple therapeutic areas, rather than a single condition. The report goes on to raise questions about the adequacy of the proposed measures for evaluation purposes, noting that the majority of the measures review whether or not certain process steps, such as information transfer or discharge planning, are performed rather than measuring the clinical outcome achieved.

Although there may be some changes from the proposed rule, and although CMS has the right to change the standards once established, the final ACO rule is likely to continue focusing on chronic care individuals as a priority. Similarly, the quality measures for these sub-populations will address medication therapies known to be effective, particularly when they are combined with programs that address the need for behavioral change:

- For quality measures that name a specific class of drug, improvements can be achieved by an increase in the appropriate use of the particular drug therapy. This may be the easiest type of behavioral change to achieve.
- For quality measures that refer to a clinical indication where an abnormal measure may indicate the appropriate use of drug therapies, the same type of improvements could be achieved, although it may take more time for the effects to be measured. For example, LDL control will require adherence to the drug therapy after it has been prescribed. In addition, quality measures with an indirect effect on drug use may increase utilization beyond the specific classes of drug therapies specifically named in a measure that could have a direct effect on utilization.

Taken together, the quality measures provide a road map for the ACOs as they plan to redesign systems and processes to increase the likelihood that the appropriate drug therapies are prescribed and programs are in place to improve an individual's adherence to the prescribed drug therapies. Understanding these measures, and the opportunities that may be presented, may be the most productive place for companies to concentrate as they assess the new proposed ACO program.

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[4] Blog posting *available at* http://healthaffairs.org/blog/2011/04/25/acos-improved-care-or-roadblocks-to-innovation/.

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Publicly Available Summaries of the ACO Proposed Rule

1) ''The Medicare ACO Proposed Rule: Legal Structure, Governance, and Regulatory Sections,'' by Douglas Hastings, Health Affairs Blog, April 5, 2011; *available at* http://healthaffairs.org/blog/2011/04/05/the-medicare-aco-proposed-rule-legal-structure-governance-and-regulatory-sections/

2) ''Launching Accountable Care Organizations—The Proposed Rule for the Medicare Shared Savings Program,'' by Donald M. Berwick, *New England Journal of Medicine*, March 31, 2011; *available at* http://healthpolicyandreform.nejm.org/?p=14106&query=home''

3) ''Proposed Rules for Accountable Care Organizations Participating in the Medicare Shared Savings Program: What Do They Say?'' Commonwealth Fund, April 14, 2011; *available at* http://www.commonwealthfund.org/~/media/Files/Publications/Other/2011/Proposed%20Rules%20for%20ACOs%20What%20Do%20They%20Say.pdf.

4) ''CMS Releases Proposed Rule on Accountable Care Organizations,'' Henry J. Kaiser Family Foundation, March 31, 2011; *available at* http://healthreform.kff.org/scan/2011/march/cms-releases-proposed-rule-on-accountable-care-organizations.aspx
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