ACO Proposed Rule Released; ACCC Hosts Conference Call

On Mar. 31, 2011, the Centers for Medicare & Medicaid Services (CMS) released the long-awaited proposed rule under the Affordable Care Act (ACA) to help physicians, hospitals, and other healthcare providers better coordinate care for Medicare beneficiaries by establishing Accountable Care Organizations (ACOs). ACOs create incentives for healthcare providers to work together to treat a patient across different care settings. The proposed rule (available on the CMS website at: *http://www.cms.gov/sharedsavingsprogram/*) calls for a 60-day public comment period. The program must be established by Jan. 1, 2012.

On April 12, ACCC hosted a conference call on the proposed rule on ACOs. During the call legal experts summarized the proposal, discussed key points, and answered critical questions about the impact ACOs may have on the oncology community. ACCC members who missed this call can hear it online at ACCC's members-only website at: *www.acccancer.org.*

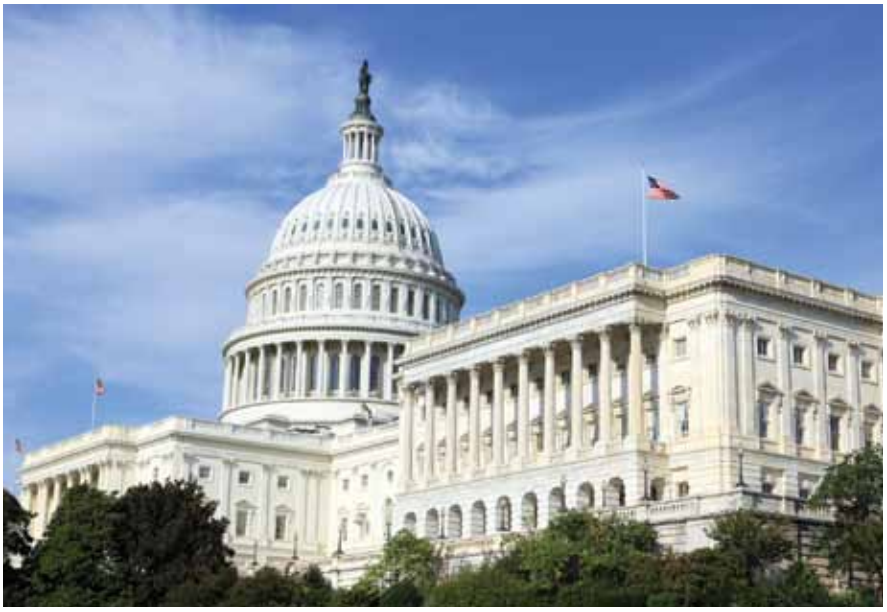
ACOs Defined

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 Medicare patients they serve. The ACO would be a patient-centered organization where the patient and providers are partners in care decisions. Patients would be assigned to an ACO retrospectively at the end of the service year. Participation in ACOs by providers is voluntary.

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 venture arrangements between hospitals and ACO professionals
- Hospitals employing ACO professionals
- Other Medicare providers and suppliers as determined by the Secretary.

The Medicare Shared Savings Program (MSSP), mandated under the ACA, will reward ACOs that lower growth in healthcare costs while meeting performance standards on quality of care and patient-centered care. ACOs will be eligible to receive a percentage of their shared savings for meeting specific targets—CMS anticipates seeing about $510 million in savings over the first three years of the program. In the proposed rule, the Secretary makes clear that certain critical access hospitals are eligible to participate in the MSSP.



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The opportunity to receive a share of these savings is not without risk, however. ACOs will be scored in three-year cycles, and for the initial three-year cycle CMS is proposing two risk models. Option 1 is a delayed-risk option where the ACOs report data all three years—the first two without penalty for failure to achieve benchmarks and in the final year ACOs have the opportunity to receive a small percent of savings for below-benchmark costs and a small penalty for above-benchmark costs. Option 2 is better suited for well-integrated organizations that are "ready made" ACOs. It offers a two-sided risk model for all three years of the cycle with the potential to receive a higher percentage of savings payments. These options are designed to offer a type of entrance ramp into ACOs for organizations strained from high start-up costs. However, starting with the second three-year cycle in 2015, all ACOs will be required to enroll in Option 2, the two-sided risk model.

Under the proposed rule, participation in the first three-year ACO cycle may be difficult for entities other than well-established, vertically integrated healthcare delivery systems. Estimated start-up costs are high—at least $1.75 million per ACO. And this may be a conservative estimate given the significant investments required in health information technology, according to ACCC's conference call presenters.

Impact on Oncology Community Uncertain

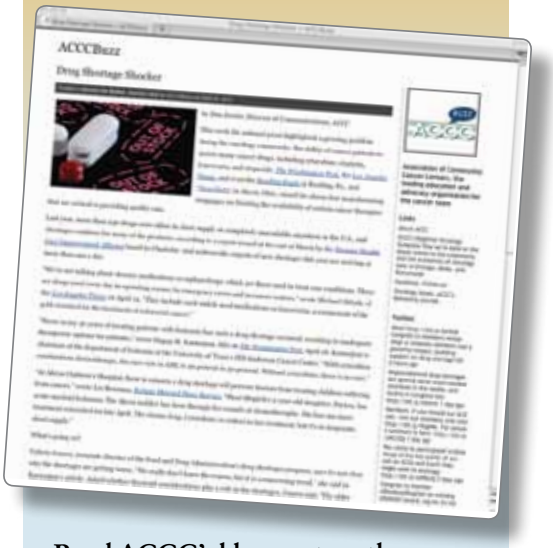
As written, the proposed rule does not seem to be conducive for oncology-centered ACOs, but it is subject to influence and change through the 60-day comment period, which ends June 6.

ACCC will likely be commenting on issues including: The amount of the shared savings proposed, the impact on community oncology facilities, the sole focus on primary care physicians and the possibility for an oncology-centric ACO, and the high technology start up costs. For more information, contact Matt Farber, ACCC's director of Public Policy and Provider Economics at: *mfarber@accc-cancer.org*.

ACCC Supports 3 Key Oncology Bills

Participants in ACCC's recent Capitol Hill Day event (see First Person on page 48) took the message to their legislators on Capitol Hill—asking for support for bills addressing the prompt pay discount and the unprecedented prescription drug shortages. ACCC is continuing to encourage its members to support to the following key pieces of legislation:

- HR 905 and S 733, companion bills in the House and Senate that would remove the prompt pay discount from the calculation of average sales price (ASP). ACCC supports this legislation, which was introduced by Representatives Gene Green (D-TX) and Ed Whitfield (R-KY) in the House and Senators Stabenow (D-MI) and Roberts (R-KS) in the Senate. These bills would remove the prompt pay discount from the ASP calculation, giving physicians a more accurate reimbursement rate for drugs.
- S 296, the "Preserving Access to Life-Saving Medications Act," which was introduced by Senators Amy Klobuchar (D-MN) and Robert Casey (D-PA). The bill shifts more responsibility on to drug manufacturers, requiring that they notify the FDA of impending drug shortages and thus hopefully creating an incentive to avoid unnecessary production stoppages.



Read ACCC's blog post on the prescription drug shortage.

For more on how to support these bills, go to ACCC's Legislative Action Center at: *http://www.accc-cancer.org/advocacy/advocacy-legislativeaction.asp*.

To read ACCC's blog, "Drug Shortage Shocker," go to: *http://acccbuzz.wordpress.com/2011/04/20/drug-shortage-shocker.*

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CMS Proposes Coverage for Provenge

In a Mar. 30 proposed decision memo, CMS indicated that the agency plans to pay for sipuleucel-T (Provenge), the autologous immunotherapy for prostate cancer. In its proposed decision memo the agency stated:

"The evidence is adequate to conclude that the use of…sipuleucel-T improves health outcomes for Medicare beneficiaries with asymptomatic or minimally symptomatic metastatic castrate-resistant (hormone refractory) prostate cancer, and thus is reasonable and necessary for that indication."

CMS declined to either endorse or prohibit off-label coverage nationwide. Instead, the agency will allow its individual local contractors to cover Provenge for certain off-label uses at their discretion. A final decision is scheduled to be issued by June 30 after CMS evaluates public comments on the memo.

Update on CMS EHR Incentive

Attestation for the Medicare EHR Incentive Program began on April 18. Eligible professionals (EPs), eligible hospitals, and critical access hospitals can attest through the CMS web-based attestation system, taking their first step toward receiving Medicare EHR incentive payments. CMS is providing multiple resources to help navigate the Medicare EHR Incentive Program, including:

- An attestation page on the CMS EHR website: *http://www.cms.gov/EHRIncentivePrograms/32_Attestation.asp*
- An online meaningful use attestation calculator (*http://www.cms.gov/apps/ehr/*) that allows EPs and eligible hospitals to check whether they've met meaningful use guidelines before they attest in the system
- An Eligible Professionals User Guide (*http://www.cms.gov/EHRIncentivePrograms/Downloads/EP_Attestation_User_Guide.pdf*)
- An Eligible Hospital and Critical Access Hospital User Guide (*http://www.cms.gov/EHRIncentivePrograms/Downloads/HospAttestationUserGuide.pdf*).

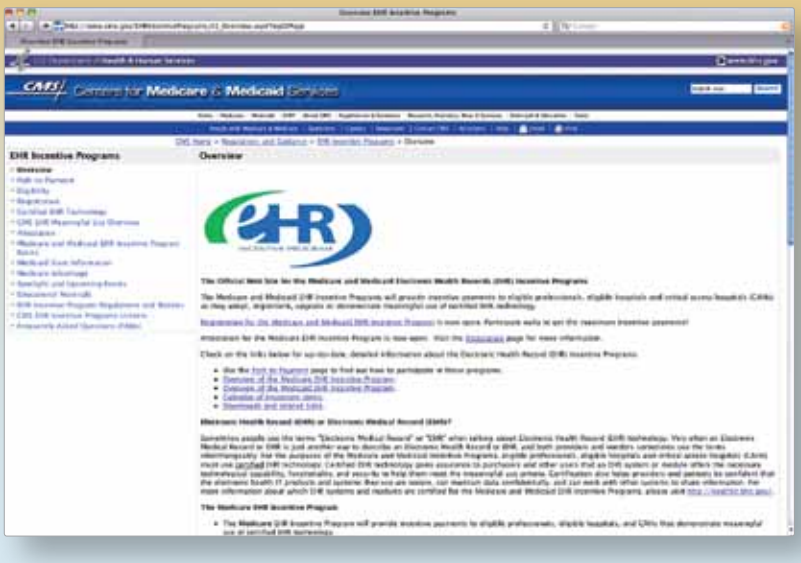
Check the EHR Incentive Program website: *http://www.cms.gov/EHRIncentivePrograms/01_Overview.asp#TopOfPage* for the latest news and updates on the program.

Medicare Program Providers Must Pay $505 Application Fee as of March 25

CMS officially announced March 22 that all institutional providers, excluding physicians and nonphysician practitioners, must pay a $505 application fee when enrolling or revalidating their participation in Medicare. The application fee provisions were included in a Feb. 2 final rule from CMS that also covered enhanced provider enrollment screening. Beginning March 25, providers must submit the calendar year 2011 fee for all enrollment and revalidation applications through Dec. 31. The fee will also be required if a provider adds a new Medicare practice location. Newly enrolling and revalidating Medicaid and Children's Health Insurance Program providers will also have to submit the $505 fee, with the exception of individual physicians or nonphysician practitioners, and providers enrolled in Title XVIII programs of the Social Security Act or a state Title XIX or XXI plan who have already paid an application fee to a Medicare contractor or to another state.

Section 6401 of the Patient Protection and Affordable Care Act included a provision for imposing an application fee on all institutional providers, excluding physicians and nonphysicians practitioners. Institutional providers, according to PPACA, are defined as any providers submitting a paper Medicare enrollment application using the CMS-855A, CMS-855B (excluding physicians and nonphysician practitioners), or CMS-855S form, or using a web-based Provider Enrollment, Chain and Ownership System application.

The full notice is available online at: *http://www.accc-cancer.org/advocacy/pdf/2011_Medicarefee.pdf*.



New resources are available on CMS's EHR Incentive Program website.