

# ISSUES

## Policy Round Up

BY CHRISTIAN G. DOWNS, JD, MHA



In this election year, U.S. healthcare policy is center stage. To help its members keep current on recent policy issues that may affect their programs and patients, ACCC provides a brief update.

### **CY 2021/2022 Medicare Advantage and Part D Proposed Rule**

On Feb. 5, the Centers for Medicare & Medicaid Services (CMS) released CMS-4190-P, which would:

- Require Part D plans to offer real-time drug price comparison tools to beneficiaries starting Jan. 1, 2022, to allow consumers to shop for lower-cost alternative therapies under their prescription drug benefit plan.
- Allow a second, “preferred” specialty tier in Part D with a lower cost-sharing amount.
- Require Part D plans to disclose the measures they use to evaluate pharmacy performance in their network agreements. This would allow CMS to track and report publicly how plans are measuring and applying pharmacy performance measures.
- Strengthen network adequacy rules for Medicare Advantage plans by codifying CMS’s existing network adequacy methodology. The proposed rule has provisions addressing access to care in rural areas and encouraging use of telehealth in all areas. For rural areas, the agency proposes to lower the percentage of beneficiaries required to live within the maximum time and distances standards from 90 percent to 85 percent. Telehealth

remains a topic of great interest to ACCC member programs. Data from the 2019 ACCC Trending Now in Cancer Care Survey found that in the next two years, 35 percent of cancer programs plan to use telehealth for delivery of genetic counseling (already difficult to access in rural areas), 28 percent for symptom consults, 28 percent for oral chemotherapy adherence and support, 28 percent for symptom monitoring (e.g., through an app), 24 percent for psychosocial counseling, and 22 percent for nutrition counseling.

Comment deadline on the proposed rule is April 6, 2020.

Together with the Medicare Advantage and Part D proposed rule, CMS released the 2021 Medicare Advantage and Part D Advance Notice Part II, in which the agency solicits comments on potentially developing measures of generic and biosimilar utilization in Medicare Part D as part of a plan’s star rating. Comment deadline on Advance Notice Part I and Part II proposals was Friday, March 6, 2020.

### **Coverage for Diagnostic Tests Using Next-Generation Sequencing**

On Jan. 27, 2020, CMS issued a National Coverage Determination that expands coverage of U.S. Food and Drug Administration (FDA)-approved laboratory diagnostic tests that use next-generation sequencing for patients with germline, or inherited, ovarian or breast cancer. CMS also gave Medicare Administrative Contractors the

ability to determine coverage of next-generation sequencing laboratory tests for other inherited cancers.

### **Importation of Prescription Drugs**

As part of the administration’s push to lower prescription drug prices, the FDA released a proposed rule and draft guidance on drug importation into the United States. The proposed rule would authorize states, wholesalers, or pharmacists to submit proposals to import prescription drugs from Canada into the United States. The rule excludes importation of biologics and infused drugs.

The FDA issued draft guidance that describes pathways that drug manufacturers would use to import prescription drugs (including biologics) into the United States that are FDA approved, manufactured abroad, and originally intended for sale in a foreign country.

The proposed rule comes after the Dec. 28, 2019, administration release of a notice of proposed rulemaking on drug importation and draft guidance. These actions follow the administration’s “Safe Importation Action Plan,” released in July 2019, which laid out pathways for importing certain prescription drugs into the United States.

### **340B Under Scrutiny**

In early January, the Government Accountability Office (GAO) released a report calling on the Health Resources and Services Administration (HRSA), an agency of the U.S. Department of Health and Human Services (HHS), to improve processes for assuring that

participating non-governmental hospitals meet 340B Drug Pricing Program eligibility requirements. The GAO report recommends that HRSA:

- Implement a process to verify that all non-governmental hospitals have contracts in place, including throughout hospitals' audit periods.
- Amend its contract reviews to include an assessment of whether contracts meet statutory requirements.
- Provide better guidance on contract reviews.

HHS agreed with the GAO recommendations except for the recommendation to set up a process to verify that all non-governmental hospitals have contracts in place. HHS says that HRSA does not have the resources to carry out the recommended verification process and that it would over-burden the agency.

Later in January, the GAO issued a second 340B report calling on HRSA and CMS to take action to prevent drug manufacturers from paying duplicate discounts under Medicaid and the 340 Drug Pricing Program. In response, HHS and 340 participating hospitals asserted that HRSA cannot legally follow the GAO's request to examine states' duplicate discount prevention policies and procedures and then act to enforce these if providers do not comply. CMS states that

HRSA lacks the authority to determine the adequacy and appropriateness of state Medicaid policies and procedures to prevent duplicate discounts. On Jan. 8, 2020, CMS issued guidance on "Best Practices for Avoiding 340B Duplicate Discounts in Medicaid" ([medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/cib010820.pdf](https://www.medicicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/cib010820.pdf)).

### **ACCC Response to Center for Medicare and Medicaid Innovation on Oncology Care First Model**


ACCC provided comments to the Center for Medicare and Medicaid Innovation's (CMMI) request for information on its concept for the Oncology Care First Model. Though applauding CMMI for making the Oncology Care First Model voluntary and envisioning a multi-payer model, ACCC urged CMMI to:

- Make significant changes to the risk tracks for purposes of performance-based payment episodes.
- Structure the prospective payment for care management and certain other services as a supplemental payment.
- Provide more detail on the methodology for the novel therapy adjustment and ensure that the final adjustment adequately accounts for the cost of innovative and often life-saving new therapies.

- Provide more details and future opportunities to comment on the Oncology Care First Model before finalizing the model.

Read the full letter at [accancer.org/advocacy](https://accancer.org/advocacy).

### **Medicaid Block Grants: Impact on Cancer Patients**

On Jan. 29, 2020, CMS released guidance that would permit states to receive a block grant for adults not otherwise eligible for Medicaid (i.e., adults younger than age 65). Dubbed the "Healthy Adult Opportunity," the agency is referring to the plan as a demonstration. In accepting the block grant—capping the state's federal funding for Medicaid beneficiaries—the state would have greater flexibility in determining benefits' coverage and benefit from a less cumbersome process for adding work requirements and other restrictions. Oncology stakeholders, along with patient advocacy groups, expressed concerns that transformation of Medicaid through block grants could reduce access to care and result in the rationing of services for the most vulnerable patient populations. As with Medicaid work requirements, the agency's legal authority to push this plan forward is likely to be the subject of litigation. 

*Christian G. Downs, JD, MHA is executive director, Association of Community Cancer Centers, Rockville, Md.*