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Commentary Overview

* The Centers for Medicare & Medicaid Services (CMS) has significantly reduced reimbursement to hospitals and cancer centers that participate in the 340B Drug Purchasing Program.

* The 340B program requires drug makers to sell their outpatient products at discounted prices to community health centers and public hospitals that serve a disproportionate number of low-income patients.

* The cuts have led to staff reductions, suspended recruitment, and reduced education and outreach efforts at the University of New Mexico Comprehensive Cancer Center.

* AACI has taken the lead in advocating against the CMS rule and has issued a survey to its 340B-eligible member centers to help safety-net hospitals make the case for the program.

CMS Reimbursement Cuts to Cancer Centers Threaten Access to Lifesaving Cancer Treatments for Underserved Patients

BY CHERYL L. WILLMAN, MD

On January 1, 2018, the Centers for Medicare & Medicaid Services (CMS) implemented a new rule that significantly reduces reimbursement to hospitals and the vast majority of cancer centers that participate in the Congressionally-mandated 340B Drug Purchasing Program. The new CMS rule (82 FR 52356) went into effect without Congressional approval and despite strong bipartisan objections from legislators in both chambers of Congress, the Association of American Cancer Institutes (AACI), and a large majority of cancer center directors from NCI-designated and emerging academic cancer centers. **The rule disproportionately harms those hospitals and cancer centers that provide care for the most vulnerable and underserved cancer patients, compounding the nation's tremendous cancer health disparities.**

Established by Congress in 1992 with strong bipartisan support, the 340B Drug Pricing Program requires drug manufacturers to sell drugs at discounted prices to hospitals and cancer centers that provide a disproportionate share of care to low-income, rural, poor, and underserved patients, to have their drugs covered by Medicare and Medicaid. The Congressional intent of the 340B Drug Pricing program is to allow hospitals and cancer centers to reinvest their savings from these drug discounts to assure patient access to high-quality care and lifesaving cancer treatments, and to develop comprehensive services.

The new CMS rule drastically reduces Medicare Part B reimbursement rates for drug purchases to hospitals and cancer centers participating in the 340B Drug Pricing Program. Under the new rule, CMS reimbursement for drug purchases has decreased from the prior rate of Average Sale Price (ASP) plus 6 percent, to ASP minus 22.5 percent, resulting in a cut of \$1.6 billion per year to the nation's public safety-net hospitals and cancer centers. This cut fully eliminates the benefit of the 340B drug pricing program to participating cancer centers. Despite claims by CMS and the drug industry, the new rule does not lower drug prices, save money for Medicare or for seniors, or reduce patient co-pays. In fact, the cost of lifesaving cancer drugs is predicted to increase significantly.

Excluded from the new CMS rule were 11 cancer centers that could previously qualify for a federal exemption from the CMS prospective payment system (the PPS-exempt cancer hospitals). The result is a profoundly disproportionate geographic impact of the CMS rule on the nation's cancer centers and cancer patients. Within the NCI-designated cancer centers, the new rule excludes 10 NCI centers (all PPS-exempt cancer hospitals) in eight states from the reimbursement cuts, while adversely

About AACI Commentary

As part of AACI's efforts to feature the work and views of its member centers, AACI publishes AACI Commentary, a quarterly editorial series. Written by cancer center leaders, each edition focuses on a major issue of common interest to AACI cancer centers.

impacting 52 NCI centers in 33 states and the District of Columbia. The disproportionately impacted cancer centers are based in (or primarily affiliated with) academic health systems, many of which deliver cancer care and conduct clinical research in large public safety-net hospitals. These centers play a critical role in bringing cancer research, clinical trials, and high-quality cancer diagnosis and treatment to patients who are more frequently poor, uninsured, and underrepresented racial and ethnic minorities. They also serve as valuable community resources, providing education, training, and outreach programs to these vulnerable populations. Thus, the CMS rule will promote disparities in access to cancer care and in outcomes for patients across our nation.

Reimbursement Reduction Hurts New Mexico Cancer Patients

As part of the UNM Health System, which includes New Mexico's largest public safety-net hospital and its primary tertiary-care hospital, the University of New Mexico Comprehensive Cancer Center provides high-quality cancer care and access to cancer clinical trials for New Mexico's neediest and its most prominent citizens. Our patients reflect the populations we serve: 52 percent are racial and ethnic minorities, predominantly Hispanic and American Indian; 55 percent are from medically underserved rural counties and American Indian Nations with high rates of poverty and cancer health disparities; and 13 percent remain uninsured despite the Affordable Care Act and New Mexico's acceptance of the Medicaid Waiver. From our cancer center's hub in Albuquerque, we provide cancer clinical trials, cancer prevention and screening studies, and clinical research activities to rural hospitals and underserved communities through a collaborative statewide network with community-based health systems and providers, touching over 85 percent of the cancer patients in New Mexico. Over the past 15 years, we have successfully built a NCI-Designated Comprehensive Cancer Center in one of the nation's poorest states. Just as the Congressionally-mandated 340B Drug Pricing Program intended, we have succeeded by reinvesting net clinical revenues in the recruitment of faculty and staff; the development of research, clinical, and community outreach programs; and training and education. We have also received significant state and philanthropic support for construction of new facilities and faculty and program development. In 2017, in our outpatient cancer clinics in Albuquerque alone, we provided over \$10 million in unreimbursed care to low-income, uninsured, or underinsured New Mexicans – a lifeline in one of America's poorest states. But with the implementation of the new CMS rule, our cancer center has experienced a \$10 million loss in net clinical revenue this year, virtually wiping out any clinical margin for continued investment in the cancer center and for support of our underserved patients.

In order to sustain our clinical mission and ensure that poor and underserved New Mexicans can continue to benefit from the fruits of cancer research, our cancer center eliminated a large number of staff; slowed or suspended key faculty recruitments that would have enhanced research and clinical programs; reduced education and training; and limited our statewide outreach. The impact is far-reaching and profound for New Mexicans.

Congress and Cancer Centers Demand Action

In September 2017, 232 members of Congress signed a letter to CMS administrator Seema Verma urging her to "abandon" the "misguided policy;" 57 senators sent Verma

a similar letter. Since then, several bipartisan bills in the House have sought to block the new rule and to stabilize or redefine the criteria for participation in the 340B program. The first, H.R. 4392, introduced by Representatives David McKinley (R-WV) and Mike Thompson (D-CA), would have inhibited CMS from implementing or enforcing the new rule. The bill has 198 bipartisan legislative co-sponsors but has not moved from the House Committee on Energy and Commerce Subcommittee on Health. Last month, Rep. Doris Matsui (D-CA) introduced H.R. 6071, the Stretching Entity Resources for Vulnerable Communities (SERV Communities) Act, which proposes to strengthen and protect the 340B program by clarifying its intent, codifying key program definitions, and rolling back the Medicare cuts. AACI has taken the lead in advocating against the CMS rule on behalf of its members. To that end, AACI sent a letter to Congressional leaders in November 2017 opposing the CMS rule and issued a press release highlighting the detrimental impact on academic cancer centers and their underserved patients. Another letter to Congressional leaders was signed by 51 AACI cancer center directors.

As part of its advocacy, AACI has issued a survey to its 340B-eligible member centers. We know the CMS rule is a major blow to underserved patients, but our hope is that the survey will provide concrete data to support and strengthen our ongoing advocacy efforts.

In December, the U.S. District Court for the District of Columbia heard a challenge to the cuts, brought by the American Hospital Association, Association of American Medical Colleges, America's Essential Hospitals, and others, arguing that the rule violates the Congressional intent of the program. The court allowed the rule to move forward on a technicality, ruling that the lawsuit was premature because the cuts had not yet gone into effect; therefore, health systems could not demonstrate harm. Further hearings are anticipated for later this summer.

The House Committee on Energy and Commerce recently held a hearing on opportunities for improving the 340B program. Two witnesses—Fred Cerise, MD, MPH, president and chief executive officer, Parkland Health & Hospital System, and Charles Daniels, PhD, FASHP, pharmacist-in-chief and associate dean, University of California, San Diego—highlighted the financial burden that the rule change would create for their facilities and patients.

Another recent development: CMS is expected to expand the number of 340B health facilities that will be impacted by payment cuts for all physician-administered drugs, drawing in offsite outpatient facilities in addition to those physically connected to 340B hospitals

If you have not already responded to AACI's 340B survey, I encourage you to do so. Our safety-net hospitals cannot make a case for the program without your input. To learn more about the program or inquire about your cancer center's survey submission contact [Jennifer Pegher](#). [AACI](#)

Representing 98 of North America's premier academic and free-standing cancer centers, the Association of American Cancer Institutes is dedicated to reducing the burden of cancer by enhancing the impact of leading cancer centers.