C L C CANCER LEADERSHIP COUNCIL

A PATIENT-CENTERED FORUM OF NATIONAL ADVOCACY ORGANIZATIONS ADDRESSING PUBLIC POLICY ISSUES IN CANCER

Hand-Delivered

October 10, 2003

Thomas A. Scully
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Ave., S.W.
Room 445-G – HHH Bldg.
Washington, D.C. 20201

RE: Medicare Program; Payment Reform for Part B Drugs,
Proposed Rule, August 20, 2003 (**CMS-1229-P**)

Dear Mr. Scully:

The undersigned organizations, representing cancer patients, providers and research organizations, write to express serious concern about the proposed rule on "Payment Reform for Part B Drugs," 68 Fed. Reg. 50428 (August 20, 2003). If the proposed rule is adopted with any of the options discussed in the Federal Register notice, there will likely be an unsustainable reduction in total payments for cancer care and an inevitable threat to patient access to quality cancer care, particularly in rural areas where treatment options may be limited.

Introduction

In a number of previous communications with the President, the Secretary of Health & Human Services (HHS), the Administrator of the Centers for Medicare & Medicaid Services (CMS), and Members of Congress, we have indicated strong support for true reform of Medicare payment policies regarding cancer drugs (which constitute the overwhelming majority of drugs at issue in the proposed rule), but we have also insisted that reform of drug payments must be accompanied by reform of the woefully inadequate methods for reimbursing the cost of administering drugs in physician offices. The proposed rule fails to address adequately the shortfall in payments for practice expenses for oncology and simultaneously offers a menu of unworkable approaches to reducing payments for drugs.

Contact: One Metro Center, 700 12th St. NW • Suite 900 • Washington, D.C. 20005

Phone: 202-508-4670 • Fax: 202-508-4650 • www.cancerleadership.org

Moratorium on Reductions in Drug Payments

The proposed rule is contrary to an explicit moratorium on decreases in payment rates for drugs imposed by Congress in section 429 of the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 ("BIPA"). Under section 429(c) of BIPA, the Secretary "may not directly or indirectly decrease the rates of reimbursement [for drugs] until such time as the Secretary has reviewed the report submitted [by the Comptroller General] under subsection (a)(2)."

That subsection imposed on the Comptroller General a number of studies and recommendations related to Medicare reimbursement for drugs and for drug administration, which were to be submitted to Congress and the HHS Secretary. Among the requisite studies and recommendations were those related to reimbursement for both drugs and the practice expense component of the physician fee schedule which currently under-reimburses oncology practices. In addition, the Comptroller General was charged with ensuring "that medicare beneficiaries continue to have appropriate access to health care services" taking into account "the potential for patients to receive inpatient or outpatient hospital services in lieu of services in a physician's office."

Perhaps most significantly, Congress was very explicit in requiring that the Comptroller General complete a task previously assigned but never completed—i.e., "a nationwide study to determine the physician and nonphysician clinical resources necessary to provide safe outpatient cancer therapy services and the appropriate payment rates for such services under the medicare program." This requirement was set forth in section 213(a) of the Balanced Budget Refinement Act of 1999 ("BBRA"), which also compelled an assessment by the Comptroller General of the adequacy of various elements of current practice expense reimbursement as well as "standards to assure the provision of safe outpatient cancer therapy services." Recommendations from the Comptroller General were required to include proposed adjustments to practice expense payment methodologies "to assure the adequacy of payment amounts for safe outpatient cancer therapy services."

Reflecting intense Congressional interest in the BBRA study, Congress stated that, "[i]n making recommendations [under BIPA], the Comptroller General shall conclude and take into account the results of the study provided for under section 213(a) of BBRA. Section 429(a)(3)(D) of BIPA. In fact, the nationwide study of these critical issues was never commenced, much less concluded. Without the BBRA study and accompanying recommendations, the Comptroller General cannot be said to have completed his BIPA report. And absent the Comptroller General's report and review of such report by the Secretary, the moratorium against decreases in payment rates for drugs remains in place.

These are not mere technical requirements. Congress made a studied decision in BBRA to require a "nationwide study" of the full range of issues related to cancer drug therapy, ranging from drug pricing to practice expense to the safety of patients in the face of proposed reforms. Noting that such study had not been completed at the time of BIPA's passage, Congress reaffirmed the importance of the BBRA study and recommendations and insisted that those results be an integral part of the Comptroller's report under BIPA. For whatever reason, that critical study and its attendant recommendations do not exist; therefore, the report contemplated by BIPA is not complete, and the moratorium accordingly remains in place. The proposed rule is thus invalid on its face.

Options to Decrease Payment Rates for Drugs

As noted above, Congress has forbidden decreases in payment rates for drugs under Medicare absent the full report required by BIPA, including the nationwide study and recommendations mandated by BBRA. Nevertheless, it is important to note that the options under consideration by CMS could prove disastrous for cancer patients in the United States, particularly in rural or other underserved communities. Each of the options presents the potential for reimbursing at least some Medicare providers less than their actual cost to acquire certain drugs. In an environment where drug acquisition costs are high and the ability of practitioners to obtain discounts is variable, drastic cuts in payment place quality care in jeopardy for many beneficiaries. Such "reform" of payment rates for drugs creates substantial disincentives for usage of the appropriate drug for treatment of cancer and undermines the quality cancer care that Medicare beneficiaries have come to expect.

Inadequate Adjustment of Practice Expense Payments

While the proposed rule is aggressive in restraining payment rates for drugs, it is timid in consideration of the corresponding issue of practice expense payments. Despite the fact that virtually all interested parties assert that excessive drug payments are offset by inadequate practice expense reimbursement, the proposed rule adopts a distinctly unbalanced approach, resulting in relatively minor revision to practice expense in the face of substantial cuts in drug payments. According to the Federal Register notice, proposed adjustments to practice expense would increase payments by a system-wide amount of $175 million. However, system-wide decreases, by CMS's own calculation, could be as much as $570 million or more. Anyone interested in quality of cancer care has to be concerned about a proposed rule that could take roughly $400 million net out of the nationwide system of cancer care for Medicare beneficiaries. If drug payments are to be reformed—which we all enthusiastically support—there must be balanced and corresponding reform to practice expense payments.

Access to Cancer Care

In the proposed rule, CMS flatly asserts, without citing any supporting data or analysis, that "we do not believe that any beneficiaries will experience drug access issues as a result of our four proposed options." 68 Fed. Reg. 50441. This assertion is a reflection of CMS's fundamental misunderstanding of the patient care issues raised by its proposal, regardless of which of the four options is adopted. Quality cancer care involves much more than simply providing access to drugs.

Patients may have access to drugs but still suffer inadequate care if the necessary infrastructure for delivering drugs and other therapy is not present. Modern cancer care requires trained oncology nurses, psychosocial and nutritional counseling and significant monitoring and follow-up. It is the evolution of that infrastructure that has permitted the successful migration of cancer care from the more expensive and often less convenient hospital setting to the physician office. The proposed rule threatens to dismantle that essential infrastructure.

While CMS has not cited any data to support its assertion that access will not suffer, surveys of physicians indicate that net payment reductions of the sort contemplated in the proposed rule will prompt many physicians to close satellite offices that serve patients in outlying areas, to curtail participation in clinical trials, and to consider declining to accept new Medicare patients. The impact on cancer clinical research was reinforced by a letter forwarded to the Administration, signed by 56 national cancer centers expressing their concern that large payment reductions would undermine clinical trial participation throughout the United States. Thus, the proposal will negatively affect not only individual patients, but also overall progress against cancer.

The scant attention to access issues in the proposed rule is particularly troubling in light of the explicit instruction to the Comptroller General to consider issues of safety and access in making its report to Congress. The Comptroller General made no real effort to review those issues, and thus his report inadequately equipped CMS to consider them in fashioning the proposed rule. The single paragraph devoted to the question of patient access in the proposed rule is shamefully overshadowed by the many pages of analysis in the proposed rule devoted to issues of drug pricing.

The proposed rule should be withdrawn until such time as CMS has sufficient data, presumably from the Comptroller General, to conduct a meaningful analysis of the all-important issue of access to quality cancer care for Medicare beneficiaries. Without such an analysis, it is unthinkable that CMS would undertake actions that could reduce by hundreds of millions of dollars the funds available to provide cancer care to our nation's senior citizens.

Inadequate and Untimely Reform

The proposed rule is not only inadequate in providing balanced reform; it is also untimely in that Congress is currently considering comprehensive legislative solutions that would address reform in a more comprehensive fashion. CMS is well aware of this Congressional activity and has in fact based some of its proposals for drug price reductions on as-yet-unenacted legislative provisions.

Congress intended CMS to act only with all the information provided by all studies, recommendations and reports mandated in both BIPA and BBRA. CMS does not yet have that information, and in fact, Congress is itself actively deliberating a solution to the dual problem of excessive drug payments and inadequate practice expense payments. In light of all these considerations, CMS should refrain from precipitate action and should decline to finalize this seriously flawed proposed rule.

Sincerely,

Cancer Leadership Council

American Cancer Society
American Society of Clinical Oncology
Cancer Care, Inc.
Cancer Research and Prevention Foundation
Coalition of National Cancer Cooperative Groups
Colorectal Cancer Network
International Myeloma Foundation
Kidney Cancer Association
The Leukemia & Lymphoma Society
Lymphoma Research Foundation
Multiple Myeloma Research Foundation
National Coalition for Cancer Survivorship
National Patient Advocate Foundation
National Prostate Cancer Coalition
North American Brain Tumor Coalition
Ovarian Cancer National Alliance
Pancreatic Cancer Action Network
The Susan G. Komen Breast Cancer Foundation
Us Too! International – Prostate Cancer Education and Support
The Wellness Community
Y-ME National Breast Cancer Organization