

CANCER LEADERSHIP COUNCIL

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

January 31, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201

Re: CMS-9898-NC, Request for Information; Essential Health Benefits

Dear Administrator Brooks-LaSure:

The undersigned organizations representing cancer patients, health care professionals, researchers, and caregivers appreciate the opportunity to comment on essential health benefits (EHB) in Affordable Care Act (ACA) plans. We commend the Centers for Medicare & Medicaid Services (CMS) for seeking advice on EHB after a decade of ACA plan experience. This is not the first CMS effort to solicit EHB advice, but this is an important inflection point – due to insurance market changes, treatment advances, and the pressing need to address health care disparities -- for assessing ACA plans and how they serve Americans who depend on their coverage. Our comments will focus on people with cancer and revisions to EHBs to ensure their access to quality cancer care.

Benefit Descriptions in EHB-Benchmark Plan Documents

CMS asks for advice about the variability in the description of EHB-benchmark plans from state to state. CMS explains how the variability in EHB-benchmark plan descriptions has occurred. The agency wrote, “These plan documents were written by different authors at different times, serving different segments of the population with different health needs, and subjected to different Federal or State requirements. We understand that the authors of the plan documents used as the EHB-benchmark plans may not have anticipated that the language used in that plan document would be used to define the EHB for a state indefinitely.”

This explanation of the EHB-benchmark plan descriptions is useful for understanding plan documents and appreciating their potential shortcomings.

The agency then suggests that they do not necessarily believe that “the ambiguity in the covered benefits and limitation in the EHB-benchmark plans has resulted in overt consumer harm.” CMS cites the lack of consumer complaints about exclusions or claims denials as evidence that plans are not excluding services that are generally understood to be covered by an

EHB-benchmark plan, even if the EHB plan document is imprecise. We are not reassured by the assertion that there have not been consumer complaints about exclusions or claims denials.

Our own organizations routinely receive complaints from patients and health care professionals about exclusions and claim denials. We concede that we cannot make firm assertions about how many of those complaints are from patients with ACA plans. Neither can we make assertions that the exclusions and denials that are the subject of complaints have occurred because plans are not meeting the standards of the EHB-benchmark as a result of uncertainty about the terms of the EHB-benchmark plan. However, we think that CMS could take steps to ensure that consumers are NOT subject to exclusions and denials that should never have occurred, if plans met EHB-benchmark standards. The agency should as a first matter set a standard for the descriptions of EHB-benchmark plans, so that plan standards are clear to issuers. In addition to providing clear guidance to issuers, clear and consistent EHB-benchmark plan documents will permit CMS to compare EHB requirements across states and will also permit the agency to ensure that issuers are meeting EHB requirements.

Typical Employer Plans

CMS asks for feedback on changes in the scope of benefits provided under the typical employer plan since 2014. This is a critical question because the state benchmarking process is defined according to the scope of benefits provided under a typical employer plan.

Individuals and families who are insured through employer plans may face serious barriers to receiving quality health care. Health care cost burdens – including the cost of premiums, deductibles, and cost-sharing – too often force patients to delay or forgo health care. Utilization management tools employed in employer plans may also hinder access to care. Exclusions of drugs from formularies may affect patient access to reasonable and necessary services. These features of employer plans have become more common in recent years, and the trends in cost-sharing structures in employer plans are having a serious adverse impact on timely access to necessary care.

In the decade from 2010 to 2020, premium contributions and deductibles for employer plans took an increasing share of workers' incomes. These costs – premium contributions and deductibles – account for 11.6 percent of median household income in 2020. This is an increase from 9.1 percent in 2010.¹

Increases in the costs of insurance coverage cause serious financial difficulties for many Americans, and those costs also deter patients from obtaining health care. Our organizations – both patient and provider organizations – see these difficulties every day. As health care professionals, we witness the decisions that patients make in delaying care, and therefore the diagnosis of cancer, and the decisions that they make about the care that they can afford. As representatives of patients, we hear daily from patients who are making choices about putting

¹ Collins SR, Radley DC, and Baumgartner JC, State Trends in Employer Premiums and Deductibles, 2010-2020, Commonwealth Fund. Accessed on January 18, 2023, at <https://www.commonwealthfund.org/publications/fund-reports/2022/jan/state-trends-employer-premiums-deductibles-2010-2020>.

food on the table, gassing up the car, or scheduling a follow-up cancer care appointment. Studies confirm what we see daily.²

A joint reporting effort of Kaiser Health News (KHN) and National Public Radio (NPR), “Diagnosis: Debt,” has revealed in stark detail the burden of health care debt among American consumers and also the impact of debt on timely access to care. The KHN-NPR effort relied on research using court records, analysis of health care systems, polling, and hundreds of interviews with health care consumers. The reporting effort does not by design focus on cancer patients and cancer care, but it has revealed much about the impact of health care costs on access to cancer care (perhaps because the high cost of cancer care puts patients at risk of debt). One lesson we take from this reporting series is that even those with insurance are too often underinsured, and the financial burdens that consumers face have an impact on their timely access to appropriate care. The trend in employer plans toward substantial cost-sharing responsibilities represents a serious financial issue for American consumers; it also affects the standards of ACA plans and adversely affects access to care.³

Pharmacy benefit managers have in recent years increased the exclusions of drugs from their formularies. In 2022, 1,156 unique prescription medicines were excluded from the standard formularies of at least one of the three pharmacy benefit managers. This is an increase of 961% from 2014, when 109 prescription medicines were excluded from one of the formularies.⁴ If employer plans accept the formulary recommendations, the implications for patients covered by those plans and ACA plans could be significant. Cancer patients may be especially seriously affected by formulary exclusions, as they often rely on combination drug therapy that utilizes multiple drugs in a class. They may also be treated with many different drugs over the course of their disease.

We discuss below the interaction of the typical employer plan’s prescription drug provisions and the formulary provisions that also govern prescription drug coverage in ACA plans.

² Collins SR, Gunja MZ, and Aboulafia GN. US Health Insurance Coverage in 2020: A Looming Crisis in Affordability – Findings from the Commonwealth Fund Biennial Health Insurance Survey, 2020. Commonwealth Fund, 2020. Accessed on January 18, 2023, at <https://www.commonwealthfund.org/publications/issue-briefs/2020/aug/looming-crisis-health-coverage-2020-biennial>.

³ The Kaiser Family Foundation Employer Health Benefits survey for 2022 found that the average premium for family coverage has increased 20% over the last five years and 43% over the last ten years. The average deductible amount for workers with since coverage and any deductible has increased 17% over the last five years and 61% over the last ten years. Although the rate of increase of both premiums and deductibles has slowed in recent years and premiums from 2021 to 2022 are comparable, consumers still shoulder significantly financial responsibility for their insurance coverage and care. Kaiser Family Foundation, Employer Health benefits 2022 Summary of Findings, accessed on January 18, 2023, at <https://files.kff.org/attachment/Summary-of-Findings-Employer-Health-Benefits-2022-Annual-Survey.pdf>

⁴ AmerisourceBergen, Skyrocketing Growth in PBM Formulary Exclusions Continues to Raise Concerns About Patient Access, May 2022.

Review of EHB

Barriers in Accessing Services Due to Coverage or Cost

We have discussed above, in the context of the typical employer plan, the impact of premium costs and deductibles and cost-sharing on access to care. As we note, the high costs of care result in financial toxicity that may burden consumers for years and result in bankruptcy. The costs of care may also cause patients to delay or forgo care altogether.

In the RFI, the agency asks about the employment of utilization management and its benefits to consumers if it reduces the cost of health care. Although we understand the potential for utilization management tools to reduce overall health care costs for the benefit of consumers and the health care system, we find instead that utilization management often limits patient access to appropriate care. These tools delay or completely block access to care all too often.

To describe the impact of prior authorization (PA), one utilization management tool employed by insurers and health plans, on access to cancer care, we refer to a Nationwide Physician Survey on Prior Authorization and Cancer Patient Care conducted by the American Society for Radiation Oncology (ASTRO) in April 2019.⁵

According to the ASTRO survey of physicians:

- 1/3 of those surveyed report that prior authorization (PA) has led to a serious adverse event for a patient in their care
- 93% said that their patients experience delays in treatment.
- 82% reported that difficulties related to the PA process led to treatment abandonment altogether
- 73% said their patients regularly express concern about the delay caused by PA
- 62% report that most PA related denials are overturned on appeal
- 1/3 report average delays of MORE THAN **five days**, a full week of standard radiation treatments
- 1/3 were forced to use a different therapy due to PA delays

These survey results are specific to PA for cancer treatment and the impact of PA on access to care. We believe that these results echo across the health care system.

We recommend that essential health benefits be defined in a way that limits the use of prior authorization so that there is meaningful access to essential benefits rather than limited access or delayed access to appropriate care.

Changes in Medical Evidence and Scientific Advancement

We are concerned that EHB-benchmark plans lag behind scientific advancements in the treatment of cancer. We identify two specific concerns related to advancements.

⁵ American Society for Radiation Oncology, Prior Authorization and Cancer Patient Care, a Nationwide Survey conducted in April 2019. Accessed on January 18, 2023, at [ASTROPriorAuthorizationPhysician-SurveyBrief.pdf](#).

EHB-benchmark plans may not include coverage of molecular diagnostic tests that are required to fully characterize a patient’s cancer and to support treatment decision-making. We are increasingly able to target therapies to cancer patients – or to recommend forgoing chemotherapy, on the other hand – if patients have access to molecular diagnostic tests. Coverage and payment for these tests may not be available due to the limitations of EHB-benchmark plans and the ACA plans that rely on those benchmarks.

In the last several years, many blood cancer patients have enjoyed the benefits of chimeric antigen receptor (CAR) t-cell therapy, a therapy that to date is personalized and specific to a patient. We understand that CAR t-cell therapy presents challenges to payers because of its delivery and overall cost, but Medicare has evaluated the therapy and taken important steps to ensure beneficiaries access to the treatment. More remains to be done to ensure Medicare coverage and payment, but much has been accomplished. EHB-benchmark plans and ACA plans designed according to them lag behind in coverage of this new therapy. CAR t-cell therapy is being investigated and incorporated into the standard of care for more types of cancer. As a result, the potential for denying access to evidence-based care that is the result of recent scientific advancement also grows. Such gaps in care – in this case related to CAR t-cell therapy – need to be addressed by a process that promptly reviews new technology and considers ways for its incorporation in EHB-benchmark plans.

We also recommend that EHB-benchmark plans include clear provisions mandating coverage of the routine patient care costs for patients enrolled in clinical trials. Medicare has a National Coverage Policy for the routine patient care costs in clinical trials, some states have clinical trials coverage requirements, and insurers in other states have entered into voluntary agreements regarding clinical trials coverage. That leaves some EHB-benchmark plans lacking in clarity about clinical trials coverage.

This lack of clarity means that many individuals enrolled in ACA plans do not participate in clinical trials, even if those opportunities are offered and represent a good treatment option. Cancer researchers, cancer care professionals, patients, and patient advocates have been working diligently to establish public policies that will encourage enrollment in clinical trials by all who are interested. Currently, there is a significant lack of diversity in clinical trials enrollment, and this lack of diversity harms those excluded from trials and the cancer research system. In many cases, we simply cannot answer questions about the efficacy of approved drugs for older Americans, Black Americans, and others who are routinely excluded from trials. EHB-benchmark plans should cover the routine patient care costs in clinical trials.

Addressing Gaps in Coverage

Coordination of Care

The RFI asks for guidance about benefits, including those related to coordination of care, which are not included in EHB-benchmarks but that perhaps should be. The RFI focuses on strategies to enhance the delivery of behavioral health services as well as approaches that might address disparities in access to quality care. CMS asks in the RFI if innovations in Medicare or other third-party payment systems should be considered as models for EHB-benchmarks.

As a community of patients, health care professionals, researchers, and caregivers, we have for many years advocated for more vibrant efforts to plan and coordinate cancer care. We believe that these services would improve: 1) quality of treatment decision-making, 2) the quality of supportive care, and 3) access to services that will ease the transitions that patients must make across the trajectory of care and into survivorship.

CMS has shown leadership in developing and implementing new codes for transitional care management and for complex chronic care management, reforms that are accomplished through updates to the Medicare physician fee schedule. These codes support services for care management and coordination and for transitions in care. We commend CMS for these efforts. We have pointed out to the agency in previous communications that these codes pay for services that are not precisely consistent with the delivery of cancer care and with transitions in the cancer care journey. As a result, these codes are not utilized by cancer care providers as CMS anticipated that they would be.

CMS has also pioneered cancer care alternative models that encourage cancer care planning and coordination.

We believe that the reform and experimentation efforts in Medicare supply lessons for services that should be included in EHB-benchmarks or in some other way provide standards for ACA plans. We have in years past recommended that the essential benefit category of “habilitative services” be defined in a way to support cancer care planning and coordination and cancer survivorship care. We urge that concept be revisited and carefully evaluated.

Telehealth

Cancer patients and health care professionals have enjoyed great benefits from telehealth, as delivered according to flexibilities that have been granted during the COVID-19 pandemic. At a time when cancer patients, including especially those who are immunocompromised, were unable or reluctant to come into health care institutions, telehealth was a safe and effective means of receiving some elements of cancer care.

In addition, the grant of telehealth flexibilities has encouraged cancer care providers to experiment with new ways to deliver care. Institutions are investigating ways to provide “cancer care at home.” We commend the experimentation but offer cautions that quality of care and safety must be protected at the same time that convenience of care at home is advanced.

We recommend that essential health benefits be expanded to include a telehealth category. We also urge that actions be taken to protect safety and quality, efforts that we understand will be difficult to undertake in the context of essential health benefits categories.

Coverage of Prescription Drugs as EHB

Currently, plans subject to EHB requirements must cover at least the same number of prescription drugs in every United States Pharmacopeia (USP) category and class as covered by the State’s EHB-benchmark plan, or one drug in every USP category and class, whichever is greater. Plans may exceed the minimum number of drugs required to be covered, and all

covered drugs would be considered EHB. In the RFI, the agency asks for advice about the use of USP Guidelines for defining prescription drug coverage. The agency also asks if the American Hospital Formulary Service (AHFS) or the USP Drug Classification (DC) developed in 2017 should be used in place of the USP Guidelines.

As we have discussed above, pharmacy benefit managers (PBMs) are increasingly excluding drugs from formularies, and those exclusions are then reflected in EHB-benchmarks and plans that must meet those benchmarks. As a result, patients may not be able to obtain the drugs that are excluded from their plan formularies. The single drug USP requirement may not address the problem created by formulary exclusions. As we also noted, consumers may forgo important drug therapies because they cannot meet cost-sharing responsibilities.

We do not believe that substituting the AHFS or USP Drug Classification for the USP Guidelines will address the access problems that we have identified. We recommend instead that the protected classes policy that is utilized in the Medicare Part D prescription drug program be incorporated in the EHB system. We understand that there is strong resistance to a policy that requires formulary inclusion of “all or substantially all” drugs in certain classes. Insurance plans and PBMs suggest that this policy limits their ability to negotiate drug prices. We are mindful of the need to control drug prices, for the benefit of individuals and the entire health care system. However, we believe that the policy for including “all or substantially all” drugs in certain classes may be the only way to protect access to lifesaving drugs for cancer patients and others with chronic and serious and life-threatening diseases that are treated by prescription drugs.

As we have explained above and over years in connection with the protected classes policy, cancer patients may require combination drug therapy and may also require a number of different drugs over the course of their disease. For many cancer patients, a prescription drug plan that may have only one drug per class or category is inadequate.

We appreciate the opportunity to comment on EHBs for Affordable Care Plans. We commend CMS for its efforts to seek input regarding EHBs.

Sincerely,

Cancer Leadership Council

Academy of Oncology Nurse & Patient Navigators
American Society for Radiation Oncology
Association for Clinical Oncology
CancerCare
Cancer Support Community
College of American Pathologists
International Myeloma Foundation
LUNgevity Foundation
Lymphoma Research Foundation
National Coalition for Cancer Survivorship
Ovarian Cancer Research Alliance
Prevent Cancer Foundation