



January 31, 2023

The Honorable Xavier Becerra  
Secretary  
U.S. Department of Health & Human Services  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

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

Dear Secretary Becerra,

CancerCare appreciates the opportunity to offer our comments to the U.S. Department of Health and Human Services (HHS or Department) in response to the Centers for Medicare & Medicaid Services (CMS) Request for Information (RFI) on issues related to Essential Health Benefits (EHB) under the Patient Protection and Affordable Care Act (ACA). CancerCare is a 79-year-old national organization that provides free professional support services and information to help people manage the emotional, practical, and financial challenges of cancer. In 2022, our staff answered more than 38,000 calls to our helpline and served clients with 90 different types of cancer in all 50 states. Our comments are informed by the stories we hear from our clients as they navigate the confusing, expensive, and frustrating process of accessing and paying for vital – and sometimes life-saving – cancer care and treatment. This RFI is issued at a pivotal moment for cancer patients as insurance plans (plans) are increasingly delaying, limiting, and/or denying access to affordable coverage of essential care and treatment.

***Benefit Descriptions in EHB-Benchmark Plan Documents***

The ACA brought about many significant and beneficial changes to our health care system and consumers, one of them being coverage of EHBs. We appreciate the tall order originally presented to those implementing the ACA on how best to establish the EHB package and the reasons behind using states' EHB-benchmark plan documents to facilitate this effort. However, as indicted by use of the word "essential" in the definition, EHBs are essential health benefits to *all* enrollees notwithstanding the state they live in or the benchmark plan in question. There is no room for the continued disparate coverage of and/or ambiguity in defining EHBs as exists in the current system, and as acknowledged by CMS.

We respectfully but strongly take exception with CMS's belief that the **ambiguity in the covered benefits and limitations in the EHB-benchmark plans** has not necessarily resulted in overt consumer harm, and the basis upon which this belief is premised. First, any harm to consumers, whether overt or otherwise, caused by ambiguity in covered benefits and limitations is reason to **ensure EHBs are clearly described in detail and applied consistently across all EHB-benchmark plans**. In addition, given the complexity of our health care system, the indecipherable language used in plan documents, and the lack of prominently displayed and easily understandable directions on how and where to send complaints, we do not believe any correlation can or should be drawn between the lack of consumer complaints and the effectiveness of states enforcing the EHB-requirements where the plan language is ambiguous or lacking in detail. Calls from patients and care partners seeking guidance on where to go and what to do when their medication was excluded or their claim denied were among the 38,000 calls CancerCare answered in 2022. Ambiguity not only leaves patients floundering as they seek cancer treatment, it



complicates the Department’s statutory obligation to periodically review and update EHBs to address existing gaps in coverage or changes in evidence, which, when left unaddressed, perpetuates disparities in coverage and potential harm to patients.

It is, therefore, with a sense of urgency that we ask the Department to review and update the EHBs as required by the ACA, to address the gaps in access to coverage or changes in the evidence base to ensure patients benefit from EHBs as intended.

We further call upon the Department to establish and implement a time period to serve as a standard interval for future “periodic reviews and updates” of EHBs and recommend staggering the two intervals to allow adequate time to ensure both a comprehensive review and subsequent update. However, to ensure patients are both protected against egregious gaps and benefit from life-altering scientific advances, a guardrail should be implemented to provide the Department with flexibility to trigger a review and/or update outside of the established standard period if credible information on these matters is revealed in the interim.

To facilitate the review and update of EHBs and address any gaps in access and/or changes in the evidence base, whether within a standardized or triggered time period, CMS should work with states and plans to **collect claims data that help identify gaps** through evidence such as denials. In addition, to increase the opportunity for direct patient input, the Department, in concert with states and plans, should develop, promote, and prominently display a standardized complaint reporting system that is patient-friendly, seamless, and easily understandable (including linguistically and culturally appropriate documents and instructions) that accurately captures, reflects, and incorporates data on harmful exclusions, claim denials, and other access, coverage, or cost barrier issues regarding EHBs. Similarly, to uphold the intent of EHBs, CMS should establish a mechanism to ensure that changes in the evidence base are timely considered and incorporated into EHBs, both within and outside any established standardized review period as the evidence dictates.

### ***Typical Employer Plans***

The RFI seeks comments on the changes in the scope and generosity of benefits offered by employer plans since plan year 2014. As we will detail in connection with barriers to access due to coverage or cost, private and public employers and plans are desperately seeking ways to lower their cost of providing health care to employees at a time when the costs for that care are increasing. This has created the perfect storm where the **scope and generosity of benefits in employer plans has declined**, while **employees pay more** than ever for reduced benefits.<sup>i</sup> In 2022, the average annual premium for employer-sponsored single coverage was \$7,911 and \$22,463 for family coverage (an increase of 43% from 2012 to 2022).<sup>ii</sup> A Kaiser Family Foundation/LA Times Survey found that four in ten adults with employer coverage had difficulty affording their premiums, deductibles, co-pays, or an unexpected medical bill, with paying medical bills before meeting their deductible presenting the greatest problem.<sup>iii</sup> In 2020, premiums and deductibles together represented 10% or more of median household income in 37 states.<sup>iv</sup>

Since employer-based coverage serves as the cornerstone of our health care system (providing insurance to more than 160 million Americans) as well as the benchmark for EHB benefits and coverage under the ACA, the implications for patients’ access to affordable coverage of essential health benefits could not be greater. The life-threatening nature of cancer, coupled with the high cost of cancer care and treatment (the National Cancer Institute calculated the average cost in the year following a cancer

diagnosis to top \$42,000<sup>v)</sup>) heightens the risk that less generous EHB-benchmark plan benefits will cause harm to cancer patients and others with serious, chronic health conditions.

### ***Barriers to Accessing Services Due to Coverage or Cost***

Employers' and plans' reduction of benefits, increased utilization management, and the shifting of more health care costs onto patients has created **dangerous barriers to access of care** for the cancer patients we serve. While understanding the original basis for the ACA to look to a typical employer plan to serve as the state benchmark for the ten categories of EHBs, the ACA also includes "**Required Elements for Consideration**" in defining EHBs that the Secretary of the Department must follow. Three of these required elements play a particularly important role in achieving the ACA's goal of preventing plans from continuing their past discriminatory practices of denying coverage or charging excessive costs for coverage to people with health conditions, disabilities, and other factors that could add to plans' costs.

Under these three required elements, the Secretary of the Department shall:

- not make coverage decisions, determine reimbursement rates, establish incentive programs, or design benefits in ways that discriminate against individuals because of their age, disability, or expected length of life;
- take into account the health care needs of diverse segments of the population, including women, children, persons with disabilities, and other groups;
- ensure that health benefits established as essential not be subject to denial to individuals against their wishes on the basis of the individuals' age or expected length of life or of the individuals' present or predicted disability, degree of medical dependency, or quality of life.<sup>vi</sup>

We ask that these required elements for consideration help guide the Department and CMS in its efforts to ensure patients have affordable access and coverage of EHBs.

As mentioned above, employers and plans continually seek to cut their costs by minimizing and/or reducing coverage of benefits (including EHBs), shifting more health care cost onto patients, and designing benefits in ways that discriminate against or deny access to medically necessary care for people with cancer and other disabilities.

The RFI asks for stakeholder input on access to **mental health services**, including behavioral health services that are EHBs. A cancer diagnosis is often accompanied by increased psychosocial and mental health needs, with one in three people with cancer experiencing mental or emotional distress, up to 25% of cancer survivors experiencing symptoms of depression, and up to 45% experiencing anxiety.<sup>vii</sup> While the ACA's coverage of mental health and substance use disorder services, including behavioral health treatment, is one of the 10 EHBs and has improved access and coverage, gaps in state enforcement of parity provisions under the Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) remain and need to be addressed.<sup>viii</sup>

**Telehealth** proved to be a critical health care delivery method during the COVID-19 pandemic for many people, and especially for cancer patients and others susceptible to severe outcomes caused by COVID-19. The telehealth flexibilities spurred by the public health emergency also helped increase access to much needed mental health care services among patients with serious diseases in a socially limited or isolated environment. Since cancer patients and others with serious illness and/or a compromised immune system will continue to confront significant health risks and isolation with or without the threat of COVID-19, expanding EHBs to include telehealth services is necessary.

In addition to asking for stakeholder input on access to mental health and substance use disorder services and telehealth, the RFI section titled *Barriers of Accessing Services Due to Coverage or Cost*, poses several questions regarding utilization management (UM) and EHBs. We express concern that the first questions posed about UM and EHBs in this RFI section focus not on patients' challenges in securing or affording EHBs, but instead on the effectiveness of plans' efforts to control costs of EHBs, and the extent that providing EHBs increases utilization and associated costs if effective cost controlling efforts are not implemented. **These questions appear misplaced and require patients and advocates to defend or justify the use and cost of benefits that are, by definition, essential.** We appreciate the subsequent questions about UM and the opportunity to provide information on what strategies patients and providers have seen implemented to reduce utilization and costs, how those strategies are applied, and the extent to which those tools curb or complicate access to medically necessary care.

**The UM tools and other practices** employers, plans, and Pharmacy Benefit Managers (PBMs) implement are neither patient-centered nor intended to encourage appropriate care at less cost to patients. UM practices are designed to lower organizational costs by erecting barriers to needed care that use unwarranted denials to discourage access to necessary treatment. They cause delays and lead to increased non-adherence by patients. Our experience indicates that these practices are designed, implemented, and enforced to reduce the employers' and payers' share of health care costs by imposing burdensome and potentially life-threatening restrictions on access to essential care and treatment while also shifting greater and unaffordable cost-sharing onto patients.

For example, a survey by the American Society for Clinical Oncology (ASCO) illustrates the serious consequences of **prior authorization (PA)** on cancer care and treatment, with nearly all respondents (n=300) reporting that PA caused harm to patients. This included 96% reporting delays in treatment, 94% reporting delays in diagnostic imaging, 93% reporting patients being forced onto a second-choice therapy, 87% reporting therapy was denied, 88% reporting patients experienced increased out-of-pocket costs, and 80% reporting disease progression.<sup>ix</sup> In addition, while almost all PBMs and health plans claim to use peer-reviewed evidence-based studies when designing their PA programs, 30% of physicians report that PA criteria are rarely or never evidence-based, and 43% report that the criteria are only sometimes supported by evidence.<sup>x</sup>

When cancer patients don't get the right drug at the right time, the length and severity of illness can increase.<sup>xi</sup> **Step therapy** is used by plans and PBMs to require patients to first try drugs that they, not the prescribing physician, prefer and which must then prove to be ineffective before the drug originally prescribed by the clinician is approved. This UM tool is designed and implemented to save money for plans and PBMs, not patients, and comes with a potentially higher "cost" of delaying timely, effective care, to treat cancer and other serious diseases. Importantly, despite payers' insistence on step therapy, oncology drugs often do not have substitutes that are equally effective and less costly. Furthermore, step therapy policies often require patients to retry treatments that have already failed, such as when a patient switches plans or the formulary changes.

**Excluding drugs** from plans' formularies is a dangerous and growing practice that imposes significant barriers to access for cancer patients and others with serious diseases. One study reported that between 2014 and 2022, one of the largest PBMs excluded 46 unique cancer medicines and supportive therapies (7% of its total exclusions during the study period). This PBM was not alone. The study reported that during the same period, two additional large PBMs excluded 32 (5% of its exclusions) and 30 (5% of its exclusions) cancer and supportive-care medicines from their respective formularies.<sup>xii</sup> With the top 3 PBMs, all owned by payers and controlling nearly 80% of the prescription drug market, the prospect for

patient-centered formularies looks dim. A PBM's drug exclusions is a burdensome, complicated, and often lengthy process that, at best, delays the patient's receipt of essential treatment, and at worst, denies the patient access to the medication altogether.

While not always considered a traditional utilization management tool, copay accumulator adjustment programs impose significant cost barriers that restrict access to essential care for patients with cancer and other diseases. These programs are designed to target assistance programs created for and available to patients with serious, chronic, and complex diseases (people with disabilities) who rely on the assistance to access their essential medication. By designing copay accumulator plans that accept copay assistance but fail to apply that amount to patients' cost-sharing obligations, plans and PBMs impose discriminatory access barriers to people with disabilities. They also violate the EHB definition of cost-sharing which includes "any expenditure required by or on behalf of an enrollee with respect to essential health benefits; such term includes deductibles, coinsurance, copayments, or similar charges, but excludes premiums, balance billing amounts for non-network providers, and spending for non-covered services."<sup>xiii</sup> Owing to an inequitable health care delivery system and ongoing health disparities, people from vulnerable populations are more likely to have a chronic condition that requires medication, compounding the discrimination caused by copay accumulator adjustment programs. <sup>xiv</sup>

One of the advances in cancer care and treatment has been the development and approval of oral therapies to treat many conditions that previously could only be treated with infused drugs. **Oral therapies** offer numerous and sometimes unique benefits, including avoiding travel to medical facilities, exposure to others who could have dangerous viruses, and increased flexibility to participate in work and family life. Notwithstanding the numerous benefits oral therapies provide to patients, their coverage under a plan's prescription drug benefit automatically increases their cost as compared to infused drugs which are covered under the medical benefit. Oral parity requires that effective therapies be affordable and accessible regardless of their delivery method.

Plans and PBMs typically place cancer and other high cost drugs on the specialty or a high tier which requires patients to pay a greater percentage of cost sharing compared to the cost sharing percentage they must pay for drugs on lower tiers. <sup>xv</sup> The rebate system contributes to the cost barriers patients encounter when they need drugs on the specialty or a high tier. In this context, rebates are monies PBMs receive in exchange for putting drugs on a plan's lower formulary tiers, thereby facilitating higher volume. Also, rebates are not reflected in the price used to calculate patients' cost share, so the percentage they pay is off a higher base price than the buyer actually paid.

Whether resulting from plans failing to count copay assistance toward patients' cost-sharing or plan designs that charge more for treatments delivered orally than by infusion, these coverage and cost barriers exacerbate the health equity crisis in our country and significantly contribute to poorer health outcomes among vulnerable populations that struggle to pay their expenses.

*When examining these and other barriers to accessing services due to coverage or cost, we ask CMS to not only review practices that discriminate against cancer patients and others with disabilities, but to affirmatively consider the health care needs of diverse segments of the population (including cancer patients and others with disabilities) as set forth in the required elements for consideration in defining EHBs.*

### ***Changes in Medical Evidence and Scientific Advancement***

There have been dramatic advances in cancer care and treatment since 2014 and it is important for these changes in medical evidence and treatment to be reflected in EHB-benchmark plans and accessible to patients. For example, through the development and availability of biomarker testing for certain cancer mutations, important information can be revealed about a person's cancer including the likely efficacy of specific treatment.<sup>xvi</sup> Being aware that biomarker testing for cancer can be called several different names, e.g., tumor testing, tumor genetic testing, genomic testing, or genomic profiling is important as it raises the risk of ambiguity and the need to carefully and consistently name biomarker testing across all EHB-benchmark plans. Not only are there varied names for biomarker testing, but commercial plan coverage and the breadth of that coverage is varied and inconsistent, providing the benefit of this testing to some and denying it to others.<sup>xvii</sup> Biomarker testing is also available for other conditions and more patients diagnosed with cancer and other diseases will benefit as evidence increases. We ask for a timely review and update to include coverage of biomarker testing as an EHB.

Another recent scientific advance in cancer is CAR T-cell therapy. Since 2017, six CAR T-cell therapies have been approved by the FDA to treat certain blood cancers and the therapy has been described by Dr. Steven Rosenberg, chief of Surgery at NCI's Center for Cancer Research (CCR) as "a standard treatment for patients with aggressive lymphomas."<sup>xviii</sup> While the therapy is covered by Medicare, the intricacies of CAR T-cell therapy and its high cost have prompted changes to its terms of coverage, which may further evolve with the science.<sup>xix</sup> We ask that CMS conduct timely and thorough reviews and updates on the inclusion of CAR T-cell therapy in EHB benchmark plans so patients may benefit from changes in medical evidence and scientific advancement.

These two examples demonstrate the need for the Department to establish and implement a time period as a standard interval for periodic reviews and updates of EHBs, as well as the need for a trigger for reviews and updates to take place outside of those standard intervals when credible information is revealed in the interim.

### ***Coverage of Prescription Drugs as EHB***

While some of the discussions above touched upon coverage of prescription drugs, we appreciate CMS including a specific opportunity to provide input on this important issue. The development and approval of new cancer drugs has brought about tremendous improvements in patients' outcomes and new drugs continue to be developed to provide even more effective treatment. Between May 1, 2016 and May 31, 2021, the FDA approved 207 cancer drugs, 14% of which were first-line therapies that displaced cancer therapies that were considered to be the standard of care for their indication.<sup>xx</sup> Unfortunately, approval of more effective drugs to treat cancer does not equate to coverage and patient access to those new treatments.

The RFI requests stakeholder input on whether CMS should consider the future use of an alternative RX drug classification standard for defining the EHB prescription drug category, such as the USP DC or others.

Plans subject to EHB requirements must currently 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 are permitted to cover more drugs, and if they do, those drugs are also considered EHBs.

Because of the complexity and individual nature of cancer (as discussed in connection with biomarker testing), patients benefit most when they have access to the full range of treatments to treat their disease. Despite multiple studies linking restricted formularies with increased medical costs and higher total healthcare spending,<sup>xxi</sup> our current system does not support an open formulary. With that being the starting point, CancerCare supports use of the more comprehensive **USP Drug Classification** (USP DC) to serve as the baseline standard. But our recommendations do not end there.

Coverage of one drug in every USP category and class is insufficient to provide patients with the range of medications often necessary to best treat a condition. Therefore, **coverage of a minimum of two drugs in every category and class** should be the new minimum requirement, which aligns with the minimum Medicare Part D requirement.

Adopting the USP DC as the new prescription drug classification standard and increasing the minimum requirement to two drugs in every USP category and class, however, will still not ensure that all patients have coverage of a drug to treat their disease or disease sub-type. We strongly urge that EHB requirements for prescription drugs adopt and enforce a **presumption of medical necessity** to facilitate coverage and access to a drug that is not on the formulary. This will help alleviate the serious harm caused to patients by burdensome and restrictive UM tools and the growing number of drugs excluded by plans and PBMs.

To best ensure patients with serious, chronic, and complex diseases have access to and coverage of the most effective prescription drugs to treat their condition, we urge the timely adoption and implementation of coverage for **all or substantially all drugs** in classes of serious, chronic, and complex diseases. This list should be comprehensive and include, but not be limited to, the current six protected classes in Medicare Part D. Applying the previous discussion on the importance of incorporating changes in medical evidence and scientific advancement, these classes should be periodically reviewed and updated to best reflect the evidence base and address patients' needs.

## Conclusion

Thank you for issuing this RFI to seek our input on EHBs. We appreciate your consideration of our comments. If you have any questions, please contact Kim Czubaruk at [kczubaruk@cancercare.org](mailto:kczubaruk@cancercare.org).



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<sup>i</sup> Making Employer-Sponsored Insurance More Affordable, Health Affairs Blog, May 17, 2021.

<sup>ii</sup> Employer Health Benefits, 2022 Summary of Findings, KFF, n.d., accessed on January 27, 2023, at [Employer Health Benefits 2022 Summary of Findings \(kff.org\)](https://www.kff.org/employer-health-benefits/2022-summary-of-findings/).

<sup>iii</sup> Kaiser Family Foundation/LA Times Survey of Adults With Employer-Sponsored Insurance, May 2, 2019, accessed January 27, 2023, at <https://www.kff.org/private-insurance/report/kaiser-family-foundation-la-times-survey-of-adults-with-employer-sponsored-insurance/>.

<sup>iv</sup> Collins SR, Radley DC, and Baumgartner JC, State Trends in Employer Premiums and Deductibles, 2010-2020, The Commonwealth Fund, January 12, 2022, accessed January 26, 2023, at

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<https://www.commonwealthfund.org/publications/fund-reports/2022/jan/state-trends-employer-premiums-deductibles-2010-2020>.

<sup>v</sup> Levey, N., “She was already battling cancer. Then she had to fight the bill collectors,” July 9, 2022, KHN, accessed January 28, 2023, at <https://www.npr.org/sections/health-shots/2022/07/09/1110370391/cost-cancer-treatment-medical-debt#:~:text=The%20National%20Cancer%20Institute%20calculated,Usually%2C%20most%20costs%20are%20covered>.

<sup>vi</sup> Pub. L. 111-148, title I, §1302, title X, §10104(b), Mar. 23, 2010, 124 Stat. 163, 896.

<sup>vii</sup> Mental Health Impacts of a Cancer Diagnosis, National Behavioral Health Network for Tobacco and Cancer Control Blog Post, September 14, 2018, accessed on January 26, 2023, at [Mental Health Impacts of a Cancer Diagnosis - #BHtheChange](#).

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<sup>ix</sup> Survey Highlights Impact of Prior Authorization on Cancer Care, Healthcare Innovation, November 23, 2022, accessed on January 27, 2023, at <https://www.hcinovationgroup.com/population-health-management/payers-providers/news/21288166/survey-highlights-impact-of-prior-authorization-on-cancer-care>.

<sup>x</sup> 2021 AMA prior authorization (PA) physician survey, <https://www.ama-assn.org/system/files/priorauthorization-survey.pdf>.

<sup>xi</sup> McCleery, John. “The Politics of Step Therapy.” *OBR Oncology*, May 2019, [obroncology.com/article/the-politics-of-step-therapy/](http://obroncology.com/article/the-politics-of-step-therapy/).

<sup>xii</sup> AmerisourceBergen, Skyrocketing Growth in PBM Formulary Exclusions Continues to Raise Concerns About Patient Access, May 2022.

<sup>xiii</sup> 45 CFR 155.20

<sup>xiv</sup> The Center for American Progress, Fact Sheet: Health Disparities by Race and Ethnicity, May 7, 2020, accessed on January 16, 2023, at <https://www.americanprogress.org/article/health-disparities-race-ethnicity/>.

<sup>xv</sup> 2021 Employer Health Benefits Survey, KFF, November 10, 2021, accessed on January 24, 2023, at <https://www.kff.org/report-section/ehbs-2021-section-9-prescription-drug-benefits/>.

<sup>xvi</sup> “Biomarker Tests and Cancer Treatment,” American Cancer Society, n.d., accessed on January 29, 2023, at <https://www.cancer.org/treatment/understanding-your-diagnosis/tests/biomarker-tests.html>.

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<sup>xviii</sup> “CAR T Cells: Engineering Patients’ Immune Cells to Treat Their Cancers,” National Cancer Institute, last updated March 10, 2022, accessed on January 27, 2023, at <https://www.cancer.gov/about-cancer/treatment/research/car-t-cells>.

<sup>xix</sup> “Does Medicare Cover CAR-T Therapy?,” Medicare.org, n.d., accessed on January 28, 2023, at <https://www.medicare.org/articles/does-medicare-cover-car-t-therapy/>

<sup>xx</sup> Benjamin DJ, Xu A, Lythgoe MP, Prasad V. Cancer Drug Approvals That Displaced Existing Standard-of-Care Therapies, 2016-2021. *JAMA Netw Open*. 2022;5(3):e222265. doi:10.1001/jamanetworkopen.2022.2265.

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