

November 27, 2017

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-9930-P
P.O. Box 8016
Baltimore, MD 21244-8016

Re: Proposed Notice of Benefit and Payment Parameters for 2019

Dear Administrator Verma:

The Leukemia & Lymphoma Society (LLS) believes that a viable exchange market, with meaningful coverage options, is essential for ensuring access to affordable, high-quality care for patients. LLS serves the needs of blood cancer patients by working to find cures for leukemia, lymphoma, Hodgkin's disease, and multiple myeloma, and by ensuring that blood cancer patients have sustainable access to quality, affordable, coordinated healthcare. We welcome the opportunity to offer the following comments.

We appreciate the Trump Administration's stated focus on increasing consumer choice and on lowering deductibles and reducing cost-sharing for consumers. Patients are experiencing high out-of-pocket costs: recent analysis of 2017 QHPs shows that the average combined deductible for silver plans is \$3,703, a 20 percent increase from 2016, and that half of silver plans charge more than 30 percent coinsurance for specialty drugs.¹ We agree that the government must take steps to make coverage more affordable and give patients more options.

Yet, we believe that many of the policies in this proposed rule will result not in high-quality care that is more affordable but, rather, in lower-quality care, higher out-of-pocket costs, and fewer meaningful choices for patients. As we stated in LLS's Principles for Meaningful Coverage,² for coverage to be truly "meaningful," it must guarantee access, promote affordability, ensure quality, and encourage stability. While this rule may, if finalized as proposed, result in the availability of more plans among which consumers can choose, we fear these plan options may not offer meaningful coverage to patients.

We are deeply troubled by the instability and uncertainty in the market that the legislative efforts to repeal and replace the Affordable Care Act have fostered. Combined with the Administration's elimination of cost-sharing reduction payments to marketplace-participating insurers, we are concerned that the uninsured rate will increase and that those who are able to keep their coverage will no longer be able to afford the care they need. Further, we are concerned that regulatory actions being publicly considered pursuant to the recent Executive

¹ Avalere Health. "Consumer Cost Continue to Increase in 2017 Exchanges." January 18, 2017. Online at <http://avalere.com/expertise/life-sciences/insights/consumer-costs-continue-to-increase-in-2017-exchanges>

² Available at <http://www.lls.org/cancercost/Principles>

Order, which aims to expand access to more affordable options, will instead imperil access to high-quality care—particularly for cancer patients and others with costly, pre-existing conditions.

We recognize that allowing states and insurers some additional flexibility has the potential to encourage innovation and promote issuer participation in the market. However, without appropriate guardrails, we believe additional flexibility could lead to a “race to the bottom,” with insurers and states shifting even more costs to consumers, covering fewer services, and providing lower-quality care.

Cancer patients’ lives depend on having access to meaningful health insurance coverage. For many cancer patients, even a short interruption in their coverage can have dire consequences for their treatment and their outcomes. Over the past year, many patients have feared they may lose access to the care they need or no longer be able to afford essential treatments as a result of rising costs and reduced federal assistance. As the Administration considers policy changes aimed at increasing flexibility in order to marginally decrease costs for healthier consumers, LLS urges HHS to consider the impact of these changes on cancer patients’ access to lifesaving care.

Provisions and Parameters for the Permanent Risk Adjustment Program (§153.320)

LLS supports improving the marketplace risk adjustment rules to promote quality and avoid steering of cancer patients and others with high cost conditions. All patients benefit when plans are adequately and appropriately compensated through an accurate and effective risk adjustment program. LLS commends CMS on its efforts to make improvements to the risk adjustment program and recommends that CMS closely monitor the impact of changes to the risk adjustment program on patient access.

Applicability of Rate Review (§154.103); Rate Increases Subject to Review (§154.200)

LLS is concerned that CMS’s proposal to increase the threshold for reasonableness review of rate increases from 10% to 15% sends a signal to issuers and consumers that CMS is not as focused as it has been in the past on ensuring that rate increases are justified by data. Given the potential that rising premiums will deter enrollment among healthier consumers, LLS believes that it is important for CMS to carefully review proposed increases to ensure they are warranted and we thus ask CMS not to finalize this policy as proposed. If CMS does finalize this proposal, we recommend that it carefully monitor the implementation of this rule to ensure that it does not result in larger rate increases.

Determinations of Effective Rate Review Programs (§154.301)

Decreasing the advance notification requirements from 30 days to 5 business days for proposed or final rate filings will further reduce the public’s already limited opportunity to offer comments on rate changes. In addition, eliminating the requirement for uniform postings will make it more challenging for both state officials and the public to evaluate and understand rate changes. We are concerned that these proposals signal a step backwards in the movement towards more transparent, participatory processes in the healthcare sector. We recommend that CMS reconsider this proposal.

Standardized Plan Options (§156.20)

We strongly discourage CMS from finalizing its proposal not to specify standardized options for the 2019 benefit year. As we have stated in previous comment letters, we believe that offering “standardized benefits” can make the benefit selection process easier and more transparent, as well as provide more certainty for patients around out-of-pocket costs. We question CMS’s assertion that standardized options, which insurers are not required to adopt, are limiting insurers’ ability to offer innovative benefit designs. In addition, more “innovative” benefit design does not inevitably mean benefit designs that will provide better, more affordable coverage for patients.

The standard plan options helped patients identify and enroll in plans with first dollar coverage for certain services, often reducing patient out-of-pocket costs. In addition to providing coverage of key services before the deductible, these plans may offer patients a more affordable option overall; premiums for standard silver plans in FFE states were, on average, 4% lower than those of non-standard plans in 2017.³

Consumers already struggle to understand plan options and to navigate the process for choosing appropriate coverage. Removing features from the website that help people compare plans and evaluate their options will mean that consumers will not have the information they need to make the best choices for themselves and their families.

Flexibility for State-Based Exchanges and State-Based Exchanges on the Federal Platform (§155.106 and §155.200)

We agree that states should be encouraged to pursue innovation. However, it is crucial that these efforts result in higher-quality, more affordable options for patients and not just lower costs to the government or produce a more favorable market for insurers. CMS can play a key role in promoting innovation, but it also must ensure that there are guardrails to protect patients.

We are pleased that CMS envisions providing assistance to states by offering access to enrollment data. While states may have unique needs, CMS can be an important resource for data and technology. There is an economy of scale to CMS serving as a central repository for data and other resources; states may be hampered in their efforts to innovate if each must develop its own tools and build its own database. LLS urges CMS to continue to develop and update the tools in which it has already invested so that it can reduce the burden on state governments to build infrastructure from the ground up.

Navigator Program Standards (§155.210)

The proposal to remove the requirement that each exchange have at least two Navigators may make it more difficult for consumers, particularly those with limited access to or ability to use technology, to seek help when considering plan options. Many patients already struggle to sign up for coverage and to understand how their medications and care needs will be covered under different plan options. In particular, we are concerned that the most vulnerable patients and consumers, including those who are sicker, older, or have limited literacy, will

³Avalere PlanScape®, a proprietary analysis of exchange plan features, December 2016. Avalere analyzed data for FFE states from the FFE Individual Landscape File released October 2016.

have even more difficulty finding a Navigator to assist them if Navigators are no longer required to have a physical presence in the area. Further, we believe it is important that at least one Navigator be a community- and consumer-focused nonprofit, to ensure that consumers are not inappropriately steered toward particular plans.

In addition, a reduction in Navigators increases the likelihood that those seeking customer support will not receive the necessary assistance and/or will experience long waits. We encourage CMS to delay finalizing this proposal until it has conducted more research to understand the impact this change would have on consumers.

Verification Process Related to Eligibility for Insurance Affordability Programs (§155.320)

While LLS recognizes the importance of program integrity, we believe that this proposal will put an undue burden on vulnerable populations and will ultimately prove to be an inefficient use of federal resources. The population to which this proposal would apply, those below 100% FPL, may have difficulty providing income verification. For example, people living below 100% of FPL may have multiple part-time jobs, be paid primarily in cash, and/or move frequently, all of which can make it more difficult to provide documentation verifying income in a timely fashion. In addition, we believe it is likely that the resources that the federal government will be required to deploy to identify and verify income discrepancies will likely outweigh any corresponding increases in program integrity.

LLS is also concerned that, if sufficient resources are not devoted to the verification system, there could be delays in the verification process that, in the interim, could lead patients to forgo necessary care for fear of incurring higher costs in the case of rejection. We caution CMS against moving forward with this proposal. However, if CMS does finalize this proposal, we believe it is essential to deploy the appropriate technical, personnel, and support resources to ensure that the process is straightforward, efficient, and predictable for consumers.

Essential Health Benefits Package (§156.100, §156.110 and §156.115)

LLS strongly opposes the breadth of proposed changes to the EHB-benchmark plans.

First, LLS believes the proposed changes—particularly the subdelegation to the states of the Secretary’s authority to set a benchmark and the redefinition of what constitutes a “typical employer plan”—exceed the Secretary’s authority under the Affordable Care Act. Under the proposed changes, CMS gives nearly unlimited authority to states to determine EHB benchmarks within a state, inappropriately subdelegating authority that, according to the Affordable Care Act, must remain with the Secretary. Further, CMS proposes to redefine a “typical employer plan” so broadly as to allow a distinctly atypical plan to become the basis for EHB. As University of Michigan Law School Professor Nicholas Bagley has noted, this change is potentially illegal:

“To know if a slate of health benefits is typical, you have to know something about how many health plans cover those benefits and how many don’t. The proposed rule eschews that comparative inquiry, and instead defines typicality with reference to the number of people who are covered by a single plan. Some random self-insured plan that excludes appendectomies could be treated as

typical, even if it's the only plan in the nation that does so. In other words, HHS wants to define a 'typical employer plan' to include atypical plans—which the agency emphatically cannot do.”⁴

Even if these changes can be made within the parameters established by the law, we recommend that CMS not finalize them, as LLS believes these changes are likely to erode important patient protections and threaten access to necessary care for cancer patients across the country.

In addition, we are concerned that the new options for developing a benchmark that CMS outlines — permitting states to adopt benchmarks from other states, replace EHB categories with categories of benefits from another state's benchmark, or create a new benchmark — will lead to year-over-year upheaval and instability in the market and a reduction in the quality of available coverage.

As it relates to the quality of coverage, we are concerned that allowing states to utilize the above range of options will lead to a “race to the bottom,” should “outlier” plans with less generous coverage become more widely adopted as benchmarks. That is, states may use the proposed process to choose the least generous coverage categories from around the country and meld them together into a new benchmark that is of poor value and which has little relation to the coverage currently offered in that state. Both outcomes would be highly inconsistent with the Congressional intent expressed in the Affordable Care Act's statutory language regarding EHB.

Regarding marketplace instability, the potential for significant annual changes in the benchmark will create an ever-moving target for plans, making it difficult for them to design benefits that incorporate their experience from the previous year. While some additional flexibility and variety among plan options has the potential to increase the choices available to consumers, we again note that increasing the number of options does not inevitably lead those options to be any better for consumers. Combined with the decreased focus on providing assistance to consumers comparing plan options, an influx of plan choices that are based on different benchmarks will make it more difficult than ever for consumers to correctly identify the plan that will provide them with the coverage they need at a price they can afford. Developing new benchmarks and educating consumers about them will also place administrative burden on the states.

Though we do believe that the federal government has an important role to play in setting guardrails for state benchmark plans, we do not recommend that CMS pursue establishing a “Federal default definition of EHB” or “establish a national benchmark plan standard for prescription drugs” in future years. While guardrails can ensure some consistency across states, a national standard could undermine the flexibility that plans need both to tailor coverage decisions to meet individual patient needs and to adapt to cover new and innovative treatments, especially where it relates to access to care for small populations like those living with rare blood cancers. In addition, the administrative burden and costs involved in developing, updating, and enforcing national standards would be significant.

⁴ Nicholas Bagley. “Trump and the Essential Health Benefits.” October 31, 2017. Online at: <https://takecareblog.com/blog/trump-and-the-essential-health-benefits>

Functions of an Exchange (§155.200) and Qualified Health Plan Minimum Certification Standards (§156.200; §156.230; §156.235)

We have several concerns about the proposed changes to the QHP minimum certification standards and the more limited role that CMS proposes to take in the process. As we stated in our comments on the proposed market stabilization rule, LLS recommends that CMS reconsider its plan to take a reduced role in regulating network adequacy. Access to robust provider networks that provide meaningful choice across the full range of providers and facilities is essential for patient access to necessary care. In particular, blood cancer patients have limited treatment options and need access to specialty providers and institutions such as National Cancer Institute (NCI) designated centers or transplant centers that have special expertise in blood cancer treatments.

We remain concerned that reliance on state network adequacy reviews, combined with the reduction in essential community provider requirements finalized in the market stabilization rule, will lead to further narrowing of provider networks. The result will be a decrease in choice for all consumers and, for blood cancer patients, decreased access to specialty expertise, increased out-of-pocket costs, and growing limitations on treatment options. Access to appropriate specialty care ensures that blood cancer patients have the best possible chance of being diagnosed correctly and immediately put on an appropriate treatment regimen. Being put on the correct treatment path not only gives a patient the best chance of successfully fighting cancer, but also reduces the likelihood that she will waste valuable time and resources on treatments that are either unlikely to or will not improve her health.

In addition, while some states have pursued innovative policies to promote network adequacy, LLS continues to believe that the federal government's reliance on state reviews will result in vast discrepancies in access across the country; patients' access to robust networks should not be contingent upon living in the 'right' state. LLS again recommends that the federal government define and implement guardrails to ensure adequate networks, establish and manage a consumer-friendly exemptions process, and ensure that consumers have the information that they need to make the best choices about their care.

If CMS does move forward with these proposals, we believe that CMS must increase its support efforts to the states and offer tools and data to ensure that state officials have the resources they need to conduct robust QHP reviews. In addition, we recommend that CMS carefully monitor the implementation of these policies to ensure that patients are not adversely affected.

Ideas for Innovative Market-Driven Programs and Value-Based Insurance Design (Other Considerations)

LLS supports movement toward a more value-centered system. We agree that innovations that both lower costs and improve outcomes should be fostered. However, we have significant concerns about the potential for issuers to abuse certain approaches that use cost-sharing to “incentivize more cost-effective enrollee behavior.” Cost-sharing for many blood cancer therapies is already high enough that it significantly lowers adherence, and higher out-of-pocket costs for patients accessing appropriate care are not the solution for rising costs.

We are also concerned about CMS's interest in encouraging issuers to offer high-deductible health plans (HDHPs) paired with Health Savings Accounts (HSAs) and promoting such plans through display options on

Healthcare.gov. HDHPs are not the best choice of plan for many patients, particularly those with serious and/or chronic illnesses, as these plans typically lack first dollar coverage for costly treatments and may therefore result in higher out-of-pocket costs for many patients. Importantly, enrollment in an HDHP is associated with decreases in the likelihood that patients will seek necessary care and adhere to their treatment regimens.⁵

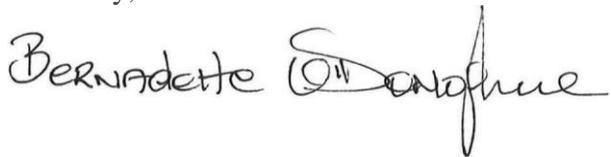
Consumers shopping for plans need even more transparency into expected costs and coverage when considering consumer-directed plans, to make sure that they can make informed decisions. While we hope any display features will make it clear to consumers that their out-of-pocket costs may be higher with an HDHP than with another type of plan, we are concerned that CMS's intent to promote such plans will result in consumers choosing a plan type that does not best fit their needs. In addition, many consumers seeking coverage through the exchanges likely do not have the ability to contribute to an HSA, meaning that encouraging the proliferation of these plans would not provide additional meaningful plan choices for them.

About LLS

LLS is the world's largest voluntary health agency dedicated to the needs of blood cancer patients. Each year, over 150,000 Americans are newly diagnosed with blood cancers, accounting for nearly 10 percent of all newly diagnosed cancers in the United States. The mission of LLS is to find cures for leukemia, lymphoma, Hodgkin's disease, and multiple myeloma and to ensure that blood cancer patients have sustainable access to quality, affordable, coordinated healthcare. LLS funds lifesaving blood cancer research, provides free information and support services, and advocates for public policies that address the needs of patients with blood cancer. Since our founding nearly 70 years ago, LLS has invested more than \$1 billion into research for cures and LLS-funded research has been part of nearly all of the FDA-approved therapies for blood cancer.

LLS appreciates the opportunity to offer its comments on the proposed rule. Should you have any questions about our comments or our organization, please do not hesitate to contact Bernadette O'Donoghue by email at bernadette.odonoghue@lls.org or by phone at 202-989-1810, or Brian Connell at brian.connell@lls.org or by phone at 202-989-1805.

Sincerely,

A handwritten signature in black ink that reads "Bernadette O'Donoghue". The signature is written in a cursive style. Below the signature is a horizontal line.

Bernadette O'Donoghue
Vice President, Office of Public Policy

⁵ Agarwal R, et al. "High-Deductible Health Plans Reduce Health Care Cost and Utilization, Including Use of Need Preventive Services." Health Affairs. October 1, 2017.

