Reducing the Cost of Cancer Care:
Policy Options from The Leukemia & Lymphoma Society
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The cost of cancer care is rising at an alarming rate, with a growing portion of those costs being shifted onto patients who already face tremendous medical and financial burdens. Increasingly, patients are unable to afford care, choosing at times to delay or even forego treatment due entirely to cost. "Financial toxicity" has become as threatening to patient quality of life as the actual diseases and conditions that patients are battling on the clinical front. At the same time, rapid increases in treatment costs year after year in cancer and other disease areas will eventually strain the overall healthcare delivery system such that patients' access to high-quality care will be severely impacted.

The Leukemia & Lymphoma Society (LLS) must take bold steps to protect and promote the interests of blood cancer patients by helping to address the unsustainable cost of cancer care. To be sure, LLS can't singlehandedly address the financial weight of our healthcare system. But our organization can and must be a voice for change, pushing toward high-value healthcare for people living with blood cancer.

With that responsibility in mind, LLS calls upon all stakeholders in the oncology ecosystem – patient organizations, drug makers, payers, providers and policymakers – to similarly embrace their duty to help serve patients by reducing the cost of cancer care. Indeed, the issue requires engagement from across our entire ecosystem. The high cost of cancer care can't be attributed to just a single stakeholder. Nor should we look to a single stakeholder to shoulder the entire burden of reform. As each stakeholder thoughtfully considers their role in this challenge, we call on each one to incorporate transparency as a standard of doing business so that together we can continue to deliver high-quality care for patients.

To that end, LLS urges its fellow stakeholders to consider the following policy options. These suggestions are organized by stakeholder group, reflecting the roles and responsibilities that – in LLS's view – correspond to each group. By offering these options, LLS hopes to initiate progress toward reducing the financial distress facing blood cancer patients.

As a preface to these recommendations, LLS issues a pledge of its own – to remain vigilant regarding the cost of cancer care when engaging in the policy sphere – and urges its fellow patient organizations to do the same. The patient voice is a powerful tool. When adopting it to speak on behalf of patients, organizations must do so with care and respect, never in a manner that will worsen the patient financial burden. With that responsibility in mind, LLS will commit to advancing only those policy solutions that:

- Offer meaningful improvements for patients;
- Increase access to benefits and services for which there's an evidence base;
- Allow utilization management to serve an appropriate role in cost containment; and
- Are data-driven and feasible to implement, both administratively and financially.

<u>Patients</u>

By virtue of their cancer diagnosis and survival experience, patients and their families are important stakeholders in the cost of cancer care debate. As such, they have the ability to humanize and personalize this issue like no other party in the cancer ecosystem. In fact, patients and families, as well as survivors, have a critical role to play in advocating for and, in fact demanding healthcare that delivers value. In addition, it should be remembered that long-term remissions and cures (when attainable) bring additional value to society by restoring patients to a productive role. Thus, LLS believes it's important

for blood cancer patients to recognize the power they have as consumers and to be thoughtful in how they use this power to encourage the drive toward a more sustainable, value-oriented healthcare system. To be clear, LLS believes that patients have a fundamental right to the care they need, and that it is wholly inappropriate to ask or pressure individual patients, who wish to be treated for their disease, to seek or accept treatments that fall below the standard of care for their particular diagnosis, whether on the grounds of cost or any other factor. Further, LLS believes that cost should never prevent a patient from accessing high quality, medically appropriate care. Indeed, those are the very reasons LLS is calling upon healthcare stakeholders across the ecosystem to work together to address the unsustainable, escalating cost of care. Yet, LLS also believes that any reforms in this area cannot succeed without engagement and support from the very patients that our healthcare system seeks to serve. With this in mind, LLS urges blood cancer patients to consider undertaking the following actions:

Recommendation 1 – Engage healthcare providers and third party payers in discussions about cost to inform decision-making

Patients should consider engaging their healthcare providers and payers in discussions about not only the clinical aspects of their care but about the cost of specific benefits and services as well. Patients should partner with their provider—and potentially their insurer—to understand the out-of-pocket expense that a patient may incur and the total cost associated with specific episodes of care, including variations that may apply depending on the provider and/or site where care will be delivered. Doing so will empower patients with the information needed to make judgments and decisions based on an array of factors, including cost. In some cases, patients may use this information to elect treatments or select providers or facilities that offer the same or even greater potential benefit to the patient but at a lower cost. Certainly, to best empower patients, more work needs to be done by provider societies, individual practitioners, and payers to develop the tools and reimbursement structures to facilitate these discussions. By expressing a desire to know more about the costs associated with individual components of their care, patients can speed and – perhaps most importantly – *influence* the development of such tools and structures.

Recommendation 2 – Seek second opinions when appropriate

When appropriate to their situation, patients should consider seeking the second opinions that can help facilitate accurate diagnosis and, in turn, effective treatment plans. From a clinical perspective, an inaccurate diagnosis could result in little-to-no improvement in a patient's condition or, worse, deterioration in a patient's health. From a financial perspective, an accurate diagnosis plays a key role in directing resources toward the treatments that offer a patient the greatest potential clinical benefit relative to their cost. Similarly, benefit may be gained by seeking second opinions at later points in the course of treatment regarding other aspects of a patient's care, particularly where multiple treat options or no standard of care exist, should any uncertainty arise around the most appropriate next step.

Recommendation 3 – Advocate for policy change & for excellent care

Whether as an individual patient or as part of an effort organized by a formal patient advocacy organization, patients should consider engaging in policy discussions concerning the cost of care to the extent that the patient's health and well-being permits. The patient voice is inherently powerful, as patients reside at the center of our healthcare ecosystem – these voices help transform the discussion from the theoretical to the practical. Consequently, as has been the case in other areas of healthcare policymaking, major stakeholder groups are spurred to action when patients bring their authority to

bear on a policy debate. Further, by engaging as an advocate in policy discussions around the cost of care, patients can help ensure that any resulting policies are patient-centered.

Patient Organizations

For many people living with a cancer diagnosis, the patient community is a major source of support. This support takes many forms and includes financial resources – for example, assistance paying premiums for health plans, co-pays for drugs, or the expense of lodging when traveling to access care. Patient organizations also work to relieve patients' financial strain by advocating for public policies that limit consumers' liability for out-of-pocket costs under their health plans. Together, these efforts ensure immediate access to care for scores of patients and, for that reason, ought to continue for the foreseeable future. But as a complement to these efforts, patient organizations ought to engage in longer-term efforts to reduce the overall cost of cancer care. To that end, LLS offers the following recommendations for patient organizations:

Recommendation 1 – Engage on Cost of Cancer Care Issues

Simply stated, patient organizations must participate in on-going debates related to the cost of cancer care, as patients reside at the center of the American healthcare system. At a minimum, patient groups should document and communicate clearly the access barriers that patients face as a result of both high prices and burdensome cost-sharing. Further, with regard to value-based contracting, patient organizations should seek out opportunities to help payers, providers, and drug makers identify and incorporate patient perspectives into their determinations of what outcomes should be incentivized.

Recommendation 2 – Deliver Responsible Patient Assistance

Patient organizations must design their financial assistance programs – which support patients struggling to afford premium, copay and travel costs associated with their care – in a manner that avoids contributing to high prices or unnecessary utilization. This can be done by adhering to best practices that are defined and publically available, such as the practices set forth by the Office of the Inspector General in the U.S. Department of Health & Human Services (HHS). Doing so will ensure, for example, that financial assistance programs do not steer patients toward a certain payer based solely on better or worse opportunities for provider reimbursement.

Recommendation 3 – Minimize Conflicts of Interest through Transparency

Patient organizations should increase transparency in relationships with for-profit healthcare companies that provide the organization with funding. This helps to ensure that funders' interests do not outweigh those of the patients that the organization seeks to serve. Transparency is increased when organizations regularly publish their list of funders, the precise amounts provided and the intended use for those funds. Transparency is also improved when patient organizations disclose revenues generated by investments in drug discovery and the manner in which those revenues are spent. Finally, patient organizations should ensure that their boards of directors are not unduly influenced by for-profit healthcare companies. Here, organizations should limit the portion of board membership that is comprised of current and former executives from for-profit healthcare companies. Boards should also have a robust policy in place for mitigating risks associated with individual board members' financial interests, and those policies should be publically available.

Policy Actions – Working with patient organizations and other healthcare stakeholders, state and federal policymakers should:

Recommendation A – Rigorously Enforce Financial Assistance Guidelines

Policymakers – in particular HHS – should work with patient organizations to improve compliance with rules governing non-profit patient financial assistance programs. Robust enforcement will increase adherence to guidelines, thereby improving the quality of financial programs available today and reducing marketplace risks associated with non-compliant programs.

Recommendation B – Develop Infrastructure for Collecting and Sharing Patient Impact Data
Patient organizations should gather and share patient data to inform value-based contracting. To facilitate those efforts, policymakers should develop the necessary infrastructure for collecting and sharing such data. This will be critically important to ensuring that new approaches to contracting reflect patient perspectives in a meaningful way.

Prescription Drug Manufacturers

Breakthroughs in prescription drug therapies for blood cancer have revolutionized the treatment of these cancers and saved untold thousands of lives over the last decade alone. Due in part to LLS research investments, the current drug development pipeline includes promising new drug therapies that will continue this trend and produce new therapies and cures for additional patients. While drug innovation has had a significant positive impact for patients, innovative new therapies often come with an extremely high price tag. The combination of high prices at the point of market entry and routine price hikes throughout the patent life of many brand-name drugs has led to prices that – if extrapolated into the medium term – could easily become unsustainable. If the healthcare system is to be sustainable, drug manufacturers have an obligation both to continue to invest in innovative new products and to recognize that drug prices must reflect the value of the drug to the patient and the healthcare system, rather than simply reflecting what the market will bear. In no particular order, LLS offers the following recommendations for drug manufacturers:

Recommendation 1 – Adopt Innovative Value-Based Payment Methodologies
In order to incentivize patient-centered innovation, prescription drugs that significantly improve important patient outcomes should be rewarded generously, in comparison to new therapies that bring limited or no benefit over existing options. In support of this goal, drug makers should partner with payers to design payment and cost-sharing methodologies that reward positive patient outcomes. Specifically, drug makers ought to enter into value-based contracts with payers, identify best practices for the continued improvement of value-based agreements and work closely with relevant patient communities to incorporate patient perspectives into positive outcome definitions.

Recommendation 2 – Develop Companion Diagnostics to Support Targeted Therapies
Advances in precision medicine have produced treatment breakthroughs that have changed the lives of many blood cancer patients – turning some blood cancer diagnoses from death sentences to chronic, manageable conditions. Continued innovation in targeted therapies will build on this progress. In addition to improving outcomes, targeted agents avoid wasting precious time and valuable system resources on interventions that would provide no clinical benefit to the patient. An important component to this precision-based approach is a diagnostic test to identify which patients will likely respond to the specific therapeutic agent. Despite the value of companion diagnostics, relatively few have been approved alongside new targeted therapies. Drug makers should take the lead in addressing the challenges that impede the development of these diagnostic tests.

Policy Actions – Working with drug manufacturers and other healthcare stakeholders, state and federal policymakers should:

Recommendation A – Strengthen Evidence Reviewed in FDA Approval Determinations

Policymakers should adopt rules that incentivize improved end points for randomized controlled trials and other improvements to the preapproval process that enhance patient, provider and insurer understanding of the drug's benefit for patients. In the same vein, policymakers should also consider how to promote a standardized process for industry assessments of post-market treatment outcomes. Such information would further stakeholder understanding of the effects of medications once provided in a real world setting outside of a clinical trial.

Recommendation B – Drive Value by Promoting Alignment between Drug Prices and Benefits

Drug manufacturers should ensure that their initial product prices and price changes during the period of exclusivity reflect the best understanding of the drug's value to patients and the healthcare system. This same value imperative should drive pricing decisions for manufacturers of generics and biosimilars. LLS supports pricing transparency efforts that would allow drug manufacturers to better inform policymakers and other stakeholders of the factors driving a particular increase in list price, including changes to the drug's anticipated benefit or value to the patient or the healthcare system and other factors. These efforts are only productive if they promote a better understanding of the information or data that leads toward the alignment between drug prices and value. In promotion of this end, federal policymakers should promote value by requiring drug manufacturers to report to HHS the initial list price for each medication offered on the market and significant changes in the list price over time. Manufacturers should be required to provide a written justification for significant changes in list price in a 12 month period. HHS should then make this reported data publicly available. Policymakers should adopt a single federal standard for this transparency, in order to avoid a patchwork of state-level transparency standards that lead to confusion on the part of patients and providers and increase costs associated with compliance to 50 differing state standards. Thus LLS opposes state-level legislative and regulatory efforts related to drug pricing transparency, including proposals to require the disclosure of internal company expenditures related to marketing or research and development.

Recommendation C – Promote a Competitive Market for Off-Patent Drugs

Generic and biosimilar products have the potential to drastically reduce costs for patients and the healthcare system. At the same time, recent pricing examples prove that biosimilar and generic markets with limited competitors do not produce the level of savings expected by payers and patients. Policymakers should take a number of steps to promote a competitive marketplace for off-patent drugs.

a. Increasing Competition to Prevent Monopoly Pricing – Policymakers should advance policies that lower generic and biosimilar prices by providing a disincentive for a manufacturer with significant market power from leveraging that power to require higher payments from patients and payers. Policies to advance this goal include: (1) providing a legal framework for the temporary, limited importation of generic products in specific cases in which a competitive market for those products does not currently exist and (2) expediting the FDA review process for generic and biosimilar products in specific cases in which there is insufficient competition to lower prices among the existing brand, generic or biosimilar alternatives.
b. Prohibiting Anti-Consumer Actions Among Drug Makers – Policymakers should provide additional authority to the Federal Trade Commission (FTC) to prevent "pay for delay" settlements that can be used by a brand drug manufacturer to inappropriately delay the entrance of one or more generic or biosimilar drug manufacturers in order to maintain monopoly pricing power. Patent settlements between such manufacturers are not always inappropriate. As a result, policymakers should provide the FTC with the authority to

judge such settlements on a case-by-case basis in order to prevent agreements that harm consumers by increasing prices.

Recommendation D – Ensure Donut Hole Relief for Patients Taking Biosimilar Products
The Affordable Care Act requires brand drug manufacturers to participate in the Medicare Coverage Gap Discount Program (MCGDP) by providing certain discount payments for drugs purchased by Medicare Part D enrollees in the "coverage gap" or "donut hole." These discounts produce significant out-of-pocket savings for patients relying on these brand-name drugs. When a biologic loses its exclusivity protections and a biosimilar product enters the market, the manufacturer of that biosimilar is not required to provide coverage gap discounts. As a result, Medicare patients could experience significant increases in their out-of-pocket costs. Policymakers should enact legislation requiring the manufacturers of biosimilars to participate in the MCGDP, in order to ensure seniors do not lose access to a drug when it is replaced on their formulary by a biosimilar product.

Health Insurance Companies & Pharmacy Benefit Managers (PBMs)
Payers play an integral role in controlling healthcare costs and facilitating affordable access to necessary care by patients with blood cancer and other chronic or life-threatening conditions. Payers help lower costs for all patients by negotiating reasonable payments for treatments as varied as surgery and prescription drugs, helping patients navigate the healthcare system, and spreading the high cost of cancer care for sicker patients across a larger pool of enrollees. Given their powerful position in the healthcare system, payers have a responsibility to continue to work with other stakeholders to develop innovative payment models that reward high-quality care and create benefit designs that promote patient access to necessary care. In no particular order, LLS offers the following recommendations for payers:

Recommendation 1 – Initiate Quality-Focused Payment Models
Payers should leverage their payments to providers and medical technology innovators to reward quality care and positive patient outcomes. Payers should enter into value-based contracts for drugs and other products, developing best practices to facilitate more widespread uptake of value-based contracting in the future. In addition, payers should incentivize healthcare providers based on their development and adoption of innovative, value-based approaches to coordinating care and sharing financial risk. Importantly, payers should work with patient organizations to identify and incorporate patient perspectives into their determinations of what outcomes should be incentivized.

Recommendation 2 – Direct Prescription Drug Rebate Savings to Patients
Pharmacy benefit managers (PBMs) should direct a significant portion of the savings they derive from negotiated pharmaceutical product rebates directly to patients taking the covered medication. This shared savings from the negotiated rebate should be reflected in the cost-sharing required of a patient at the point of sale. In promotion of this end, PBMs should report publicly how they use the savings generated by negotiated rebates. This published information should include data detailing the portion of rebate dollars directed toward (1) lowering cost-sharing for patients purchasing the medication, (2) reducing plan premiums for all enrollees and (3) supporting administrative support and profit for the PBM/payer. This information should be delineated by therapeutic class in order to understand how a plan's rebate structure and benefit design impact patients with a variety of medical conditions.

Recommendation 3 – Reduce Financial Toxicity for Necessary Care
Payers should adopt value-oriented benefit designs that are tied to evidence-based protocols that incorporate patient perspectives regarding optimal outcomes and side effects. This value-oriented, evidence-based approach would help remove existing financial and bureaucratic barriers between patients and necessary treatments. If patients are pursuing the best option for their diagnosis,

condition and preferences, then there is no benefit to subjecting them to hundreds or thousands of dollars in out-of-pocket costs.

a. Prescription Drugs – In the case of valuable pharmaceutical therapies, high out-of-pocket costs financially punish the most vulnerable patients, deter adherence to appropriate therapies, and degrade patient outcomes. Payers should ensure their benefit designs limit the amount of cost-sharing required of a patient in any given month, in order to promote therapy adherence. Similarly, payers should eliminate those utilization management requirements for pharmaceutical therapies that are not in line with evidence-based protocols. Such protocols should be determined in close, transparent consultation with patient organizations and consistent with clinical treatment guidelines published by relevant medical societies.
b. Medical Expertise – Many types of cancer are both rare and complex, requiring specialized medical expertise often not available within a plan's negotiated physician network. For too many patients, high out-of-pocket costs limit their ability to access this specialized expertise. Consequently, many of these patients will not receive an accurate diagnosis, which in turn may prevent them from initiating the proper treatment plan. Payers should adopt network rules and benefit designs that ensure cost-sharing does not become a barrier for patients who need to access specialized expertise at key intervals to determine treatment regimens and guide significant treatment decisions. To advance this goal, payers should provide a patient-friendly mechanism to request and access such expertise from out-of-network providers as needed.

Policy Actions – Working with payers and other healthcare stakeholders, state and federal policymakers should:

Recommendation A – Build Consensus for Payment Models for Curative Breakthroughs
Policymakers must help drive consensus on how the healthcare system will pay for major curative breakthroughs associated with a high cost. In the past several years, payers have grappled with reconciling the exciting patient benefits of breakthrough Hepatitis C cures with the high system cost of providing these therapies to a sizable patient population. Public payers have an important role to play in developing the payment structures necessary to pay for similar therapies for cancers, Alzheimer's disease and other serious conditions. In support of this goal, policymakers should provide Medicaid and Medicare administrators the flexibility – for example, through a pilot project – to explore alternative payment models for costly, curative treatments.

Recommendation B – Modernize Regulations to Facilitate Innovative Payment Models
Policymakers should encourage value-based arrangements between payers and prescription drug manufacturers. Such arrangements require initial flexibility on the product price. The following reforms would help facilitate innovation in this area: (1) reforming the Medicaid best-price regulations and anti-kickback protections to allow contracting arrangements that include financial adjustments based on patient outcomes, (2) providing sufficient latitude in communications between drug makers and PBM/payers in advance of a product's approval in order to allow the sharing of information necessary to develop innovative payment models and (3) encouraging the use of indication-specific payment for medication that is used to treat various diseases in order to help develop and manage value-based agreements for drugs that differ in value for various indications.

Recommendation C – Hold Payers Accountable for Recommendations Suggested Above
Many of the actions recommended above require payers and PBMs to act against short-term financial gain and such action – however necessary – is often difficult in highly-competitive markets. Where

payers fail to act, policymakers must construct the rules necessary to focus the insurance industry's market forces on incentivizing quality care rather than avoiding and deterring the sick from receiving the care they need. For example, in support of Recommendation 3, LLS will continue to advance policy solutions that reduce financial toxicity, including oral parity protections at the state and federal levels for patients taking self-administered anti-cancer therapies, regulatory limits on monthly cost-sharing for medications and restrictions on punitive co-insurance cost-sharing requirements. We hope to continue to partner with payers and other stakeholders to develop policy mechanisms to support patient-focused cost containment by payers.

Hospitals, Doctors & Other Healthcare Providers

Healthcare providers are the face of the healthcare system to most patients. Providers have a broad charge, including determining an accurate diagnosis, identifying the care that best suits the needs and preferences of the patient, and helping that patient address the physical, emotional, bureaucratic, and financial barriers that too often prevent patients from receiving the care they need. Whether they are individual practitioners or major hospital systems, healthcare providers should utilize their significant influence to create change that streamlines access to appropriate care while containing system costs. Providers should partner with other stakeholders to design and implement the innovative payment systems necessary to reward value over volume, avoid administrative decisions that could end up increasing costs for patients and help patients understand the cost information necessary to inform care decisions. In no particular order, LLS offers the following recommendations for healthcare providers:

Recommendation 1 – Improve Efficiency and Ensure Service Prices Reflect Their Value

Providers should ensure that the prices they charge for their services reflect the value of the services they provide. Following a blood cancer diagnosis, many patients undergo a number of costly interventions, ranging from blood and imaging tests to, in some cases, bone marrow transplantation. These diagnostic and therapeutic services are extraordinarily important for the patients who require them, but the cost for many of these services is onerous, if not prohibitive.

a. Risk-Sharing Payment Models – Providers should adopt innovative approaches to coordinating care and sharing financial risk with payers in order to promote efficiency and optimal patient outcomes.
b. Value-Based Payment Models – Actions toward aligning services with their value should include providers partnering with payers to pioneer value-based agreements that test and refine best practices to facilitate more widespread adoption of value-based payment models.

Recommendation 2 – Avoid Consolidation Decisions that Increase Costs

In an effort to deliver care efficiently and effectively, providers across the country have been consolidating through mergers and acquisitions. While these changes can improve patient care in some ways, providers should avoid consolidation decisions that increase costs to patients and the system. For example, hospital systems should consider the cost impact on patients of purchasing private oncology practices. Such consolidation of physician practices into hospital systems risks increasing patient cost-sharing tied to higher hospital payment rates.

Recommendation 3 – Empower Patient Decision-Making with Cost Information

Providers should incorporate cost of cancer care discussions into routine treatment planning to help patients understand potential financial toxicity and promote choices that are informed by all the necessary information. Provider societies – as well as individual practitioners – have embraced the

notion of engaging with individual patients on this topic, but more work needs to be done to develop the tools, reimbursement structures, and culture necessary to empower patients to make judgments and decisions based on what factors matter most, including cost. This effort will be bolstered by increased transparency regarding price information from all stakeholders, including providers.

Policy Actions – Working with providers and other healthcare stakeholders, state and federal policymakers should:

Recommendation A – Remove Financial Incentive Related to Provider-Administered Drugs
Policymakers should adopt changes that address perverse incentives in the buy and bill system for prescription drugs covered by an insurer's medical benefit – particularly the system governing reimbursement for drugs provided under Medicare Part B. Policymakers should realign this system to prevent financial incentives that increase provider revenue based on the price of the underlying medication. Such reforms have the potential to reward value and eliminate unnecessary spending, without adversely affecting patient access to vital medications in the outpatient and physician office settings. At the same time, any restructuring of this system should acknowledge that changes to this system have the potential to impact millions of patients. As a result, policymakers should be measured and transparent in their reforms, incorporating processes to collect and assess the impact of significant changes on patient outcomes.

Recommendation B – Hold Providers Accountable for Recommendations Suggested Above
Many of the actions recommended above require providers to act against short-term financial gain and such action – however necessary – is often difficult in highly-competitive markets. Where providers fail to act, policymakers must construct the rules necessary to focus providers on incentivizing quality care rather than protecting or increasing revenue. For example, in support of Recommendation 2, policymakers should consider establishing site-neutral payment systems for public insurance programs, in order to ensure that reimbursement incentives do not drive consolidation decisions and that consolidations do not increase patient out-of-pocket costs.