



March 1, 2019

The Honorable Lamar Alexander  
Chairman  
Senate Committee on Health, Education, Labor, and Pensions  
428 Dirksen Senate Office Building  
Washington, DC 20510

Dear Chairman Alexander:

On behalf of the more than 1.3 million Americans living with a blood cancer diagnosis, The Leukemia & Lymphoma Society (LLS) appreciates the opportunity to provide recommendations to help address America's rising healthcare costs. As an organization at the forefront of the fight to cure cancer, LLS knows that the cost of care associated with a blood cancer diagnosis continues to rise and have a significant impact on all stakeholders in the healthcare system, particularly patients. We receive over 20,000 calls to our Information Resource Center (IRC) annually, the vast majority of which pertain to the cost burden of cancer.

The cost of cancer care is projected to reach \$173 billion in 2020—a 39 percent increase from a decade ago.<sup>1</sup> Such spending growth is simply unsustainable, and the direct impact on patients poses a threat their ability to access their treatment. In response to cost growth in recent years, payers and policymakers have often passed the burden to patients in the form of increased cost-sharing and changes that erode the quality of the care accessible to cancer patients.

Therefore, it is imperative for organizations like LLS to stand up for the patients, survivors, and caregivers by advancing solutions that bend the cost curve without sacrificing patient care. With that goal in mind, LLS launched our Cost of Cancer Care Initiative in May 2017, putting forward more than two dozen potential policy solutions and other recommendations aimed at reducing the cost of care.<sup>2</sup> These recommendations called upon all stakeholders in the healthcare system—patients, patient organizations, drug makers, payers, providers, and policymakers—to similarly embrace their duty to help serve patients by responsibly reducing the cost of care.

While we have been pleased that policymakers have adopted several of the recommendations we made in 2017, far more progress is needed to make the cost of treating cancer sustainable. LLS appreciates your call for concrete ideas to help achieve our shared goals, and we offer the following 31 policy recommendations for Congress to help lower healthcare costs and incentivize care that improves outcomes for patients.

## **REALIGN INCENTIVES TO DRIVE DOWN COSTS**

### **Modernize Risk-Sharing Mechanisms in Medicare Part D**

The current Medicare Part D catastrophic benefit design provides insufficient incentives for plans to negotiate for lower patient and government spending on certain drugs. In fact, the current Part D benefit and subsidy structure financially rewards Part D plans that have higher utilization of prescription drugs

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<sup>1</sup> National Institutes of Health. "Cancer costs projected to reach at least \$158 billion in 2020." Accessed at <https://www.nih.gov/news-events/news-releases/cancer-costs-projected-reach-least-158-billion-2020>.

<sup>2</sup> The Leukemia & Lymphoma Society. Cost of Cancer Care Initiative. Accessed at [www.lls.org/CancerCost](http://www.lls.org/CancerCost)

with a high list price, as long as the drug manufacturer also provides a high rebate to the plan.<sup>3</sup> This structure creates a significant incentive for Part D plans to maximize rebates, even if those rebates drive up drug list prices.

Although Part D plans and drug manufacturers benefit from this structure, patients and taxpayers end up paying more.<sup>4</sup> Patients are required to pay even more out-of-pocket, since their cost-sharing is typically based on a percentage of the drug's list price. Meanwhile, these incentives have ballooned taxpayer subsidies provided under the Part D program's reinsurance phase.<sup>5</sup>

These perverse incentives are unsustainable, and it is time for policymakers to restructure plan incentives to promote contracting practices that limit financial exposure for patients and the government. To this end, Congress should restructure the Part D benefit design to reform the proportion of catastrophic benefit phase spending for which payers and the government are responsible. Rather than the government covering 80 percent of plan spending during the catastrophic phase of the Part D benefit, the program should require plans to cover 80 percent. Similar proposals have been included in the President's Fiscal Year 2019 (FY19) Budget<sup>6</sup> and in the June 2016 MedPAC Report to Congress,<sup>7</sup> and the Center for Medicare & Medicaid Innovation (CMMI) is in the early stages of launching a demonstration project to address this problem.<sup>8</sup>

### **Expand Site-Neutral Payment in Medicare**

Vertical consolidation between hospital and physician office settings continues to rise, driven in part by the ability for the hospital entity to receive higher hospital outpatient reimbursements for services performed at the facility that had previously been considered a physician office. According to the Government Accountability Office (GAO), between 2007 and 2013, the number of vertically consolidated physicians nearly doubled from 96,000 to 182,000.<sup>9</sup> Further, a 2016 study found that the proportion of chemotherapy infusion delivered in a hospital increased from 15.8 percent in 2004 to 45.9 percent in 2014 in the Medicare population.<sup>10</sup>

Expanding site-neutral payment—the practice of paying equally for services whether they are associated with a physician practice or an outpatient hospital setting—has the potential to lower patient out-of-pocket costs and reduce unnecessary Medicare spending. To that end, Congress should require CMS to expand Medicare site-neutral payment policies. The President's FY19 Budget Proposal endorsed a policy to require equal payments for some services regardless of whether patients are treated in an off-campus

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<sup>3</sup> Milliman. (2016). The AIDS Institute, Financial Incentives in Medicare Part D. Accessed at [www.theaidsinstitute.org/sites/default/files/attachments/Milliman%20Report%20-%20Final.pdf](http://www.theaidsinstitute.org/sites/default/files/attachments/Milliman%20Report%20-%20Final.pdf)

<sup>4</sup> Dusetzina SB, Conti RM, Yu NL, Bach PB.(2017) Association of Prescription Drug Price Rebates in Medicare Part D With Patient Out-of-Pocket and Federal Spending. *JAMA Intern Med.* 2017;177(8):1185–1188. doi:10.1001/jamainternmed.1885

<sup>5</sup> Hayes, T. (2018). Redesigning Medicare Part D to Realign Incentives. American Action Forum. Accessed at: <https://www.americanactionforum.org/research/redesigning-medicare-part-d-realign-incentives-1/>

<sup>6</sup> HHS. (2018). Putting America's Health First, FY 2019 President's Budget for HHS.

<sup>7</sup> MedPAC (2016) Chapter 6: Improving Medicare Part D. *Report to Congress: Medicare and the Healthcare Delivery System.*

<sup>8</sup> CMS. (2019) Part D Payment Modernization Model Fact Sheet. Accessed at <https://www.cms.gov/newsroom/fact-sheets/part-d-payment-modernization-model-fact-sheet>

<sup>9</sup> GAO (2015) Increasing Hospital-Physician Consolidation highlights Need for Payment Reform. Accessed at <https://www.gao.gov/assets/680/674347.pdf>

<sup>10</sup> Milliman (2016) Cost Drivers of Cancer Care: A Retrospective Analysis of Medicare and Commercially Insured Population Claim Data 2004-2014. Accessed at <https://www.communityoncology.org/wp-content/uploads/sites/20/2018/07/Trends-in-Cancer-Costs-White-Paper-FINAL-20160403.pdf>

hospital outpatient facility or a physician's office, which the Administration estimated would save the Medicare program \$34 billion over 10 years.<sup>11</sup>

In addition to saving taxpayer dollars and reducing patient out-of-pocket costs, equalizing payments between these sites of service would weaken the incentive for provider consolidation, which would also produce long term costs savings and provide patients with additional options for their care.

### **Reform 'Buy & Bill' System in Medicare Part B**

Medicare Part B's 'buy-and-bill' system of reimbursement for provider-administered drugs creates perverse financial incentives that increase provider revenue based on the price of the underlying medication. Reforms to the 'buy-and-bill' system of reimbursing physician offices for the price of physician-administered drugs 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. Congress should hold the Centers for Medicare & Medicaid Services (CMS) accountable for testing various reforms that address perverse incentives in the 'buy-and-bill' system for prescription drugs provided under Medicare Part B. Given the critical role Part B plays in providing access to appropriate treatment for many cancer patients, reform proposals should begin as demonstration projects and expand based on robust and transparent review of the demonstration's results related to savings and patient outcomes.

### **Bring Transparency to Drug Pricing**

The cost of prescription drugs is incredibly high, particularly for the therapies targeted to treat conditions found only in a small subpopulation of patients like those living with certain blood cancer subtypes. Patients understand that groundbreaking treatments often come with a high price tag. Yet, with high initial prices and significant year-over-year price increases becoming more common, patients and payers should hold manufacturers accountable for ensuring that the price of a drug is commensurate with the benefits—clinical and economic—that the drug provides. Greater transparency around how prices are shaped by the clinical and economic data available for a drug and/or patient population would help all stakeholders better understand the appropriateness of a launch price and price changes.

To promote transparency related to value, Congress should require the Department of Health & Human Services (HHS) to publish annually a list of certain drugs with information about the alignment between their pricing and the drug's clinical and economic benefits. Specifically, HHS should identify, within each drug class and for a given year, ten drugs in each of the following categories: (1) newly-approved branded drugs with the highest initial list price, (2) branded drugs with the highest increase in list price over the same period, and (3) generic and/or biosimilars drugs with the highest increase in list price, using a metric that most accurately reflects changes to cost burden relative to generic and biosimilar drugs. Each drug on this list should be identified publicly, and the manufacturer of each listed drug should be required to provide HHS a written justification drawing on the clinical and/or economic data that led to the highlighted prices and/or price changes.

## **AVOID WASTEFUL SPENDING ON UNNECESSARY CARE**

### **Eliminate Medicare Spending on Drug Waste**

Drug waste due to the manufacture of oversized vials of cancer medications is estimated to cost Medicare and commercial insurers nearly \$3 billion a year.<sup>12</sup> A 2016 study of the top 20 infused cancer treatments sold in the United States found that 18 of them were sold in "one-size-fits-all" single-use vials that were too

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<sup>11</sup> HHS (2018) FY 2018 Budget in Brief.

<sup>12</sup> Harris, G. (2016) Waste in Cancer Drugs Costs \$3 Billion a Year, Study Says. *The New York Times*. Retrieved from <https://www.nytimes.com/2016/03/01/health/waste-in-cancer-drugs-costs-3-billion-a-year-a-study-says.html>

large for the typical patient.<sup>13</sup> Due to safety regulations, drugs in excess of the patient's dosage can only be used for other patients in rare and specific situations. As a result, in the vast majority of cases, the excess medication is discarded. Yet, patients and payers must still pay for the full vial of medication even though as much as 37 percent of the contents will be thrown away.<sup>14</sup>

Fortunately, we know that drug waste is a solvable problem. Many of the same medications sold in the U.S. are also sold in Europe in smaller vial sizes that allow providers to customize the dosage for each patient and drastically reduce waste. To address the incentives that lead to oversized vials in the U.S., Congress should pass the Recovering Excessive Funds for Unused and Needless Drugs (REFUND) Act (S. 551), which would curb Medicare Part B spending on the portion of the drug vial that is never given to the Medicare beneficiary. The REFUND Act would require manufacturers to reimburse the Medicare program for the federal taxpayer spending on drug vial contents that were wasted due to vial size, and a portion of that reimbursement would be passed along to reimburse Medicare beneficiaries who were required to pay out of their own pocket a 20 percent coinsurance for drug that they never received. This reform will eliminate the existing profit incentive for drug manufacturers to produce drugs in packaging that guarantees substantial wasted product.

### **Ensure Access to Optimal Treatment Planning**

Improving access to accurate diagnosis and optimal treatment planning reduces spending on wasteful interventions, while ensuring patients are receiving the right care. Many types of cancer are both rare and complex, requiring specialized medical expertise often not available within a plan's negotiated physician network. Increasingly narrow networks in health insurance plans threaten to limit access to necessary specialty care, including diagnostic and treatment planning services and stem cell transplant services for patients with blood cancer.

In a 2014 study, LLS found that among health insurance plans available in select states, only a limited number of National Cancer Institute-designated cancer centers or transplant centers were in-network facilities for plan enrollees.<sup>15</sup> For too many patients, high out-of-pocket costs associated with seeking treatment from an out-of-network provider limit their ability to access this specialized expertise. In the past two years, the U.S. Food & Drug Administration (FDA) has approved over 35 treatments for blood cancer, and specialized expertise is essential to accessing these life-saving treatments in a timely manner to avoid costs associated with less-effective or inappropriate treatments.

Additionally, without access to expertise available at facilities like these NCI-designated cancer centers, many of these patients will not receive an accurate diagnosis, which in turn may prevent them from initiating the proper treatment plan. For example, experts believe that as many as 40 percent of less common lymphomas may be inaccurately diagnosed, which is especially concerning given that the exact classification drives patient treatment.<sup>16</sup> Every dollar spent treating a patient for an inaccurate diagnosis with a protocol that will not work for their actual condition is a dollar wasted. To prevent spending from being wasted on treatments being prescribed due to an inaccurate diagnosis, Congress should require federally-regulated insurance plans, including Medicare Advantage, to 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.

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<sup>13</sup> Bach Peter B, Conti Rena M, Muller Raymond J, Schnorr Geoffrey C, Saltz Leonard B. (2016) Overspending driven by oversized single dose vials of cancer drugs *BMJ* ; 352 :i788

<sup>14</sup> *Ibid.*

<sup>15</sup> Milliman. (2014) Cost Drivers of Cancer Care: A Retrospective Analysis of Medicare and Commercially Insured Population Claim Data 2004-2014. Accessed at <http://us.milliman.com/uploadedFiles/insight/2014/four-states-individual-exchange-policies.pdf>

<sup>16</sup> Chan, JK, Kwong, YL. (2010) Common misdiagnoses in lymphomas and avoidance strategies. *The Lancet Oncology* VOLUME 11, ISSUE 6, P579-588.

Specifically, payers should establish a streamlined process to allow patients with cancer and other serious conditions to access specialty expertise from out-of-network providers, with patient cost-sharing identical to in-network care and counting toward the maximum out-of-pocket limits.

### **Expand Access to Less-Costly Palliative Care**

Palliative care focuses on providing patients with relief from the symptoms and stress of a serious illness. This specialized medical care is provided by a team of doctors, nurses, social workers, and other healthcare providers who work together with a patient's other doctors to provide an extra layer of support. Palliative care is appropriate at any age and any stage in a serious illness and can be provided along with curative treatment. By relieving complex pain and symptoms, palliative care improves a patient's ability to tolerate medical treatments and also empowers patients to play a greater role in their own care by facilitating communication between patients, caregivers and providers across the care continuum.

Using palliative care services has also been shown to reduce costs to patients and the healthcare system. Better care for high-risk, high cost patients leads to a reduction in the reliance on 911 calls, emergency department visits, hospital admissions and readmissions and leads to consistent and substantial reductions in associated healthcare spending.<sup>17</sup> Palliative care results in fewer crises, reducing hospital utilization and resulting in overall cost savings. Despite the clear benefits of palliative care to patients and the healthcare system, the availability of these services does not meet the need. To further promote palliative services and ensure a well-trained palliative care workforce, Congress should pass the Palliative Care and Hospice Education and Training Act, which would increase the availability and quality of palliative and hospice care.

## **EMPOWER PATIENTS TO PROMOTE VALUE**

### **Promote Patient Decision-Making with Transparent Cost Information**

Transparent information around the costs and benefits of a patient's treatment options empowers the patient and their clinician to compare potential interventions based on their value to the patient. Facilitating decision-making focused on a treatment's value will reward higher-value interventions and limit utilization of less valuable interventions, particularly those that are accompanied by higher costs. Although real-time benefit e-prescribing tools (RTBTs) that can provide relevant cost information at the point-of-prescription have only recently begun to be incorporated more broadly into the physician workflow, these tools have enormous potential. Indeed some payers have found these tools, and the discussions they promote between patients and providers, can have a significant impact on spending. For example, CVS Health has noted that incorporating these tools into clinical practice has facilitated a switch to a lower-cost prescription for 40 percent of prescriptions, saving an average of \$130 per prescription filled when a switch has occurred.<sup>18</sup>

Medicare Part D beneficiaries would benefit from having these tools incorporated into the Part D program, and CMS is considering moving in that direction beginning as early as the 2020 plan year.<sup>19</sup> Congress should require Part D plans to implement RTBTs that provide patients and prescribers with real-time information on a beneficiary's out-of-pocket liability for each of their treatment options.

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<sup>17</sup> Agency for Healthcare Research and Quality: System-integrated program coordinates care for people with advanced illness, leading to greater use of hospice services, lower utilization and costs, and high satisfaction. [www.innovations.ahrq.gov/content.aspx?id=3370](http://www.innovations.ahrq.gov/content.aspx?id=3370).

<sup>18</sup> Leonetti, C. (2018) Proven Savings with Real-Time Prescription Benefits. *CVSHealth*. Accessed at <https://payorsolutions.cvshealth.com/insights/proven-savings-with-real-time-prescription-benefits>

<sup>19</sup> CMS (2018) Contract Year (CY) 2020 Medicare Advantage and Part D Drug Pricing Proposed Rule (CMS-4180-P).

### **Facilitate Competition through Consumer-Friendly Plan Transparency**

When shopping for coverage during enrollment periods, consumers do not have access to clear and transparent information about the amount they would be required to pay as their share of the cost of a medication. This is due largely to the prevalence of coinsurance, a cost-sharing technique that requires consumers to pay a percentage of a drug's total cost. Plan formularies typically represent coinsurance as a percentage only – e.g. “30%” or “45%” – with no accompanying information that consumers can use to translate that percentage to an actual dollar amount. Thus consumers must select and enroll in a plan without a full understanding of the affordability of one plan's drug benefit versus another.

This lack of transparency poses a real threat to patient well-being: patients are more likely to abandon treatment when the cost of their care is high, a dynamic that is exacerbated when patients are unable to anticipate and plan for the precise out-of-pocket cost of their care. This lack of transparency is harmful to the marketplace as well, as it diminishes competition among plans.

In order to facilitate greater transparency regarding cost-sharing for medications:

- 1) Congress should require CMS to improve Medicare Plan Finder to convey important information on out-of-pocket drug costs so that consumers can judge their health care options based on complete information about the impact of their decision on their financial and physical health, and
- 2) Congress should require qualified health plans (QHPs) to provide transparency regarding the plan's prescription drug formulary, including meaningful cost-sharing information, to consumers during the open enrollment process. At a minimum, QHPs should be required to include for every covered drug a range of out-of-pocket spending for the prescription (e.g. \$-\$\$\$\$ OR \$0-10, \$11-25...\$500+, etc.)

### **FACILITATE VALUE-BASED AGREEMENTS (VBAs)**

#### **Remove Impediments to Public & Private VBAs**

When financial incentives reward volume of care delivered without considering quality or health outcomes associated with that care, we face a risk that system and out-of-pocket costs will increase without improving health outcomes. In an effort to address this dynamic, payers and providers have begun entering into value-based agreements and outcomes-based agreements, whereby a payer pays for drugs, for example, based on how well the therapy works for the payer's treated enrollees.

Both private and public payers have shown increased interest in these kinds of payment agreements. Medicaid agencies in three states—Colorado, Michigan, and Oklahoma—have received approval from CMS to enter into outcomes-based contracts with drug manufacturers, whereby certain manufacturers will be reimbursed based on how well the medication works for patients in their Medicaid programs. Several commercial payers have entered into similar contracts: a payer survey conducted in 2018 found that 25 percent of payers had in place outcomes-based contracts.<sup>20</sup> But the full extent to which these types of arrangements are being utilized in the private market is not well understood. For example, a recent study found that up to 70 percent of value-based contracts are not publicly disclosed.<sup>21</sup>

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<sup>20</sup> Avalere. (2018). Health Plan Interest in Outcomes-Based Contracts Increasing. Accessed at <https://avalere.com/press-releases/health-plan-interest-in-outcomes-based-contracts-increasing>

<sup>21</sup> Mahendraratnam, N; Sorenson, C; Richardson, E; Daniel, G.H.; Buel, L; Westrich, K; Qian, J; Campbell, PharmD, H; McClellan, M; and Dubois, R.W. (2019) Value-Based Arrangements May Be More Prevalent Than Assumed. *The American Journal of Managed Care*.

Additional support from policymakers would help to facilitate the full-benefit of this type of contracting. To this end, Senators Bill Cassidy (R-LA) and Mark Warner (D-VA) recently drafted legislation to amend the Social Security Act to promote VBAs for payers, hospitals, and clinics.<sup>22</sup>

In order to facilitate greater uptake, monitoring, evaluation, and public reporting of VBAs:

- 1) Congress should reform the Medicaid best-price regulations and anti-kickback regulations to allow contracting arrangements that include adjustments based on patient outcomes.
- 2) Congress should hold CMS accountable for clarifying to the states the process by which a state can gain the flexibility necessary to experiment with innovative VBAs. Congress should require CMS to report to Congress each year on the impact of VBAs in state Medicaid programs in terms of both program savings and patient outcomes.

### **Maximize Value Information for VBAs**

LLS believes that value-based agreements have the potential to establish incentives that promote high-value products and make drugs more accessible to patients. Yet, in order to best assess a product's value, stakeholders need accurate information on the product's costs and benefits. The FDA's accelerated approval of drugs that address an unmet medical need relies on the drug's effect on a surrogate endpoint or an intermediate clinical endpoint. Using surrogate or intermediate clinical endpoints can save valuable time in the clinical trial process, and it has significantly accelerated patient access to oncology drugs that meet these standards. At the same time, this expedited process inevitably leads to more uncertainty surrounding a drug's clinical benefit at the time of approval. Indeed, five percent of oncology drugs receiving accelerated approval between 1992 and 2017 were eventually withdrawn from the market.<sup>23</sup>

Confirmatory, post-approval trials are required by FDA as a condition of expedited approval. These post-approval studies are meant as a protective measure, providing a mechanism to flag any alarming safety signals that could emerge as a result of the treatment and confirming expectations of the drug's clinical benefit. We are concerned by reports that manufacturers do not always adhere to post-approval requirements and timelines.<sup>24,25</sup> Without timely and consistent adherence to post-approval data requirements, providers, patients, and payers have little understanding of the effects of medications in terms of both efficacy and adverse events.

In order to maximize the information available to all stakeholders to maximize the potential of value-based agreements, Congress should require the GAO to study the most effective mechanism(s) for leveraging the FDA's post-approval requirement/commitment authorities to ensure that manufacturers provide timely information that can inform the understanding of drug's clinical costs and benefits following expedited approval.

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<sup>22</sup> Protecting Patients from Surprise Medical Bills Act, S.3592. 115<sup>th</sup> Congress (2018). Accessed at <https://www.cassidy.senate.gov/imo/media/doc/Discussion%20Draft-%20Protecting%20Patients%20from%20Surprise%20Medical%20Bills%20Act.pdf>

<sup>23</sup> Beaver JA, Howie LJ, Pelosof L, et al. (2018) A 25-Year Experience of US Food and Drug Administration Accelerated Approval of Malignant Hematology and Oncology Drugs and Biologics: A Review. *JAMA Oncol.*;4(6):849–856. doi:10.1001/jamaoncol.2017.5618.

<sup>24</sup> GAO. (2015) FDA Expedites many Applications, But Data for Postapproval Oversight Need Improvement. Accessed at <https://www.gao.gov/products/GAO-16-192>

<sup>25</sup> Zettler M, Nabhan C. (2018) Fulfillment of Postmarketing Requirements to the FDA for Therapies Granted Oncology Indications Between 2011 and 2016. *JAMA Oncol.*;4(7):993–994. doi:10.1001/jamaoncol.2018.0610

## **ELIMINATE BURDENSOME COST-SHARING FOR PATIENTS**

### **Cap Out-of-Pocket Costs in Medicare Part D**

LLS is deeply concerned about unsustainably rising patient out-of-pocket costs in the Medicare Part D program. The combination of escalating list prices and the Part D benefit design leads patients who rely on costly medications to face enormous cost-sharing in January and February of each plan year, requiring the beneficiary to pay thousands of dollars for their first prescription of the year.<sup>26</sup> Increasingly, patients continue to experience high cost-sharing throughout the year, since the five percent cost-sharing required under the catastrophic phase of the benefit can still require hundreds of dollars each month.

These costs have a real and dangerous impact on treatment adherence.<sup>27</sup> A recent study published in the *Journal of Clinical Oncology* found that high out-of-pocket costs limit access to novel oral cancer medications.<sup>28</sup> Specifically, the study found that nearly one third of patients whose out-of-pocket costs were between \$100 to \$500 and nearly half of patients whose out-of-pocket costs were more than \$2,000 failed to pick up their new prescription for an oral cancer medication. By comparison, only 10 percent of patients who were required to pay less than \$10 at the time of purchase did not pick up their medications. Delays in picking up prescriptions were also more frequent among patients facing higher out-of-pocket costs.

Cancer patients in employer health plans, individual health plans, Medicaid, and Medicare Advantage plans often depend on their annual out-of-pocket cap to provide some limit to the amount they must pay for life-saving care. Yet, patients who access their treatment through Medicare Part D do not have this key protection. Creating an out-of-pocket spending cap in Part D plans would dramatically lower seniors' cost-sharing for costly and often lifesaving drugs. Today, more than one million Part D beneficiaries enter the catastrophic phase of the Part D benefit, and many are forced to spend \$10,000 or more per year to maintain access to their cancer treatment.<sup>29</sup> An out-of-pocket cap in Part D would save these seniors hundreds—and often thousands—of dollars each year. Yet, to be meaningful, an out-of-pocket cap must limit the cost-sharing required in the first two months of the year. If policymakers establish an out-of-pocket cap of \$5,000 per year yet still require beneficiaries to provide that full amount in the first two prescriptions filled each year, many beneficiaries will still be left without meaningful access to their therapies.

To address this crisis, Congress should establish a monthly cap on out-of-pocket expenses in Medicare Part D. Such a cap would provide an important financial protection to Part D beneficiaries and would break down a barrier to treatment for the tens of thousands of seniors who are currently unable to obtain their cancer drugs due to cost.

### **Share Prescription Drug Rebates with Patients**

Rebates provided by a drug manufacturer to Pharmacy Benefit Managers (PBMs) often benefit all other parties except the patient taking the drug in question. We understand that savings from manufacturer

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<sup>26</sup> Doshi, J; Li, P; Pettit, A.R.; Dougherty, J.S.; Flint, A; and Ladage, V. (2017) Reducing Out-of-Pocket Cost Barriers to Specialty Drug Use Under Medicare Part D: Addressing the Problem of "Too Much Too Soon" *American Journal of Managed Care*.

<sup>27</sup> Doshi, J; Li, P; Huo, H; Pettit, A.R.; Kumar, R; Weiss, B.M.; and Huntington, S.F. (2016) High Cost Sharing and Specialty Drug Initiation Under Medicare Part D: A Case Study in Patients With Newly Diagnosed Chronic Myeloid Leukemia. *American Journal of Managed Care*.

<sup>28</sup> Doshi, J; Li, P; Huo, H; Pettit, A.R.; Armstrong, K. (2018) Association of Patient Out-of-Pocket Costs With Prescription Abandonment and Delay in Fills of Novel Oral Anticancer Agents. *Journal of Clinical Oncology* 36, no. 5.

<sup>29</sup> Cubanski, J. Neuman, T. Orgera, K. (2017) No Limit: Medicare Part D Enrollees Exposed to High Out-of-Pocket Drug Costs Without a Hard Cap on Spending. *Kaiser Family Foundation*. Accessed at <https://www.kff.org/report-section/no-limit-medicare-part-d-enrollees-exposed-to-high-out-of-pocket-drug-costs-without-a-hard-cap-on-spending-issue-brief/>



rebates may be applied to plans' or PBMs' operational activities or used to help slightly lower premiums for all plan enrollees. However, premiums are not beneficiaries' only financial responsibility. Patients who are most in need, like those undergoing cancer treatment, are disproportionately burdened with other cost-sharing responsibilities, including high coinsurance payments.

Establishing in Medicare Part D an appropriate rebate amount to be passed onto patients at the point of sale would put money back in seniors' pockets and balance cost-sharing responsibilities in a way that is sustainable for beneficiaries, plans, and manufacturers. To that end, Congress should mandate a Part D rebate pass-through policy to help stem rising patient out-of-pocket costs by requiring a portion of the Part D rebates that manufacturers already pay to plans to be passed on to beneficiaries, reducing cost sharing for a given medication at the point-of-sale. CMS has publicly considered requiring point-of-sale rebate sharing but has not finalized a specific proposal to do so.<sup>30</sup>

To be clear, sharing rebates at the point of sale is not a panacea, as rebates vary markedly depending on the drug class. In an analysis conducted for LLS, we determined the impact of various rebate sharing proposals on patients with different conditions. Given the combination of small rebates typically provided by the manufacturers of branded oncology drugs with the high list price of those drugs, cancer patients would likely see a small savings in terms of their total out-of-pocket costs (4.4 percent savings for one example beneficiary on a common drug for chronic myeloid leukemia) but a significant savings in terms of real dollars (\$466 for the same beneficiary). While the savings for many patients may be small in comparison to their total out-of-pocket costs in Part D, sharing rebates at the point of sale would be a step in the right direction of lowering costs for patients who rely on prescription therapies.

### **Protect Cancer Patients from Burdensome Drug Cost-Sharing**

Scientific breakthroughs have dramatically changed the way cancer is treated. Unfortunately, insurance benefit design has not kept pace with the development of new self-administered treatments, leaving patients with burdensome out-of-pocket costs for some drugs. Traditional IV-administered cancer treatments are typically covered under a health plan's medical benefit, often requiring patients to pay a moderate copay. Oral and other self-administered treatments are usually covered under a health plan's pharmacy benefit. This discrepancy often results in high out-of-pocket costs through coinsurance, which requires patients to pay a percentage of the overall cost of the medicine. Patients who rely on an oral drug to fight their cancer can face hundreds or thousands of dollars more in cost-sharing than patients who take an IV drug—even if the two drugs cost the same to the health plan.

Over the past decade, 43 states have stepped forward to adopt a policy solution called “oral parity” that has solved this insurance benefit design problem for patients by preventing health plans from applying different cost-sharing to oral and self-administered medicines. While these state laws protect patients on state-regulated plans, cancer patients need Congress to extend these same protections to the 60 percent of privately-insured patients whose coverage is federally regulated. Congress should pass the Cancer Drug Parity Act, which would ensure that patients experience the same cost-sharing for all cancer treatments, including oral therapies, regardless of how they are administered.

### **Prevent Surprise Medical Bills**

Patients are understandably frustrated by a system that allows a provider at a facility in their insurer's network to require a patient to pay exorbitant bills for services they believed to be covered by their insurance. We appreciate that policymakers are developing a variety of innovative approaches, based in part on the efforts of state policymakers to address this problem. Congress should establish a framework for surprise medical bills that ensures patients are held harmless in terms of cost-sharing for care

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<sup>30</sup> Pagliarulo, N. (2017) Proposed Medicare policy could shift drug rebates to consumers. *Biopharmadive*. Accessed at <https://www.biopharmadive.com/news/proposed-medicare-policy-could-shift-drug-rebates-to-consumers/511221/>

unknowingly received by an out-of-network provider at an in-network facility or for emergency services received at an out-of-network facility.

## **PROMOTE COMPETITION TO DRIVE DOWN DRUG PRICES**

### **Ensure Generic Competitor Access to Product Samples**

Certain behaviors by brand pharmaceutical companies have delayed the introduction of generics and biosimilars to the market, leaving only the more expensive branded products available for patients and the healthcare system. For example, some companies use Risk Evaluation and Mitigation Strategies (REMS) Elements to Assure Safe Use (ETASU) requirements or other distribution protocols to avoid sharing samples of their drugs with companies seeking to make generic or biosimilar versions of the biosimilar product. LLS supports the use of REMS, including those with ETASU and other distribution protocols; without such conditions, a product may not otherwise be available to patients due to its overall risk profile. However, some companies have used these requirements to delay the market entry of generics and biosimilars, leaving patients and the healthcare system with limited, expensive options. To address this problem, Congress should pass legislation to prevent branded companies from using REMS ETASU processes to refuse to sell samples of their products to potential generic or biosimilar competitors. LLS believes this solution should be paired with robust patent reforms to prevent companies from patenting REMS methods or systems.

### **Promote Single Shared Systems (SSS) for REMS Compliance**

LLS strongly supports SSS REMS as a SSS is typically more efficient to administer and creates only a single obstacle that patients and their healthcare providers must navigate. However, while LLS strongly supports SSS REMS, experience has shown that some application holders have stymied negotiations over development of an SSS with their would-be generic competitors, thereby delaying the introduction of the lower cost, equivalent products into the marketplace. In a choice between a single drug with a single REMS or multiple, competing drugs under two comparable REMS, LLS strongly supports a competitive marketplace and multiple REMS. To that end, Congress should provide FDA sufficient resources to manage the process of encouraging the adoption of SSS REMS compliance while also approving waivers, where appropriate, to facilitate competition when competitors will not agree to a SSS.

### **Prevent the Patenting of REMS Processes**

LLS continues to observe anticompetitive conduct by application holders that hinders the entry of generic competitors into the market, resulting in higher costs for patients, payers and the healthcare system. While the FDA can encourage and support positive behavior and shame companies that engage in blocking and delaying tactics, the agency's statutory authority remains unchanged and limited. LLS encourages Congress to pursue the following patent reforms that will reduce the risk of infringement that applicants confront from REMS-related patents:

- 1) Congress should require FDA to stop listing patents related to REMS methods or systems in the Agency's Orange Book and de-list such patents currently in the Orange Book. Though current FDA practice is to list REMS patents in the Orange Book, such listings may be invalid. This has significant consequences as such listings allow brands to obtain an automatic 30 month stay of generic approval.
- 2) Congress should pass legislation deeming REMS methods or systems patents as within the "prior art," thereby limiting patent claims that branded companies have used to delay generic competition on REMS products. While the FDA mandates the use of REMS in certain situations, patents should not be permitted to bottleneck compliance with FDA requirements. This solution would limit patent claims that branded companies use to delay competition.

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### **Prevent ‘Pay-for-Delay’ Agreements**

Generic and biosimilar products have the potential to drastically reduce costs for patients and the healthcare system. However, recent pricing examples prove that biosimilar and generic markets with limited competitors do not produce the level of savings expected by payers and patients. Further, some companies have engaged in tactics to delay the entry of generics and biosimilars to the marketplace. To address these issues, Congress 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. We recognize, though, that some patent settlements between such manufacturers are not always inappropriate. As a result, Congress should provide 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. Congress should pass legislation, such as the Preserve Access to Affordable Generics and Biosimilars Act (S. 64), which would strengthen the hand of the FTC in preventing brand pharmaceutical companies from compensating generic and biosimilar manufacturers to delay the market entry of generics and biosimilars competition. In legislation such as S.64, we support the clarification of FTC authorities, the presumptions regarding anticompetitive effect of patent settlements between manufacturers, and the inclusion biosimilars.

### **Prohibit Shielding Patents through Tribal Sovereignty Immunity**

LLS continues to observe troubling practices that forestall the entry of generics and biosimilars to the marketplace. To address one of the most recent practices, LLS supports legislation that limits the ability of manufacturers to avoid United States Patent and Trademark Office (USPTO) review of weak patents by “renting” their patents to Native American tribes. The rental of sovereign immunity is a transparent attempt to thwart a robust USPTO review process and shield weak patents from generic competition. Congress should pass legislation, such as the Preserving Access to Cost Effective Drugs (PACED) Act (S. 440), to clarify that tribal sovereign immunity does not preclude patent review and enforcement by USPTO, federal courts, and the International Trade Commission.

### **Explore Patient-Friendly Remedies for ‘Product Hopping’**

Increasing the availability of generic drugs helps to create competition in the marketplace, which in turn, helps to make treatment more affordable and increases access to healthcare for patients. FDA has determined that having a second generic drug on the market significantly reduces the prices of average generics by almost half the cost of a brand-name drug. In fact, when multiple generics enter the market, the price can fall dramatically, by as much as 80 percent.<sup>31</sup>

One common strategy utilized by some brand name manufacturers to extend their initial monopolistic market position is “product hopping” – a practice whereby customers are moved from one branded drug to another very similar version of the drug that enjoys additional market exclusivity due to later patent expirations. This anti-competitive tactic raises complicated issues under patent law, antitrust law, the Hatch-Waxman Act and state drug substitution laws.<sup>32</sup>

The Trump Administration recently included a proposal in a Medicare program proposed rule that would allow Part D plans to remove the new formulation of an older oncology drug from their formularies in order to convince manufacturers to not engage in product hopping. While LLS understands the

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<sup>31</sup> FDA (n.d) Generic Competition and Drug Prices. Accessed at

<https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/ucm129385.htm>

<sup>32</sup> Shotlander, D. (2017) United States: Pharmaceutical Antitrust Update: Courts Address How And When Product Hopping May Violate The Antitrust. *Laws. Mondaq*. Accessed at

<http://www.mondaq.com/unitedstates/x/594504/Antitrust+Competition/Pharmaceutical+Antitrust+Update+Courts+Address+How+and+When+Product+Hopping+May+Violate+the+Antitrust+Laws>

Administration's intent in proposing this policy change, it would unfortunately thrust patients into the middle of a battle between drug manufacturers and payers—threatening patient access to necessary oncology drugs. LLS believes approaches such as this Administration proposal would likely fall short of solving the problem of product hopping and would create a new barrier to patient access. Accordingly, Congress should investigate the issue of product hopping by requiring the GAO to study this practice and identify potential remedies or penalties for ending production of old formulation of drug without evidence of clinical benefit of new formulation.

### **Prevent Disinformation about Biosimilars**

A key factor in the slow growth of the biosimilars market in the U.S. stems from the efforts of certain reference product sponsors to disseminate false and misleading information that casts doubt about the safety and efficacy of biosimilars in the minds of patients and prescribers. This misinformation communicated to payers is hindering the development of reimbursement policies that could help encourage biosimilar use and patient access.

In some cases, manufacturers of biologics are denigrating biosimilars in their promotional activities by implying that there are clinical differences in safety or efficacy between their product and the product's biosimilar, in violation of the Food, Drug and Cosmetic Act (FDCA). Under the FDCA, prescription drug advertising, including biologics advertising, may not make an unsubstantiated comparison representing or suggesting that a drug is safer or more effective than another drug (21 C.F.R. § 202.1(e)(6)(ii)). Because the FDA has found that a product is biosimilar to the reference product, this means that there are no clinically meaningful differences between the two products, and the biosimilar is safe and effective for its intended use.

- 1) The Bad Ad Program is an outreach program designed to educate healthcare providers about the role they can play in helping the agency make sure that prescription drug advertising and promotion is truthful and not misleading, and incorporate biosimilar examples in its course and educational case studies. Educational materials about biosimilars that the FDA develops for healthcare professionals, payers, formulary committees, and other stakeholders should call out the types of reference product sponsor claims the agency would likely deem violative and explain a simple process for reporting such promotions to the agency. Congress should encourage the FDA to exercise its authority under the Bad Ad Program, through sufficient appropriations and accountability measures.
- 2) FDA should assure it has robust and visible processes for handling complaints regarding false or misleading promotions of biosimilars. Congress should hold FDA accountable for streamlining this process and allocate sufficient resources to their swift investigation and resolution. We suggest that there be a seamless handling of biosimilar promotional complaints to assure there is no confusion as to whether the Center for Drugs Evaluation and Research (CDER) or the Center for Biologics Evaluation and Research (CBER) is responsible for the matter. LLS further recommends that claims suggesting biosimilar inferiority should be elevated internally within the Office of Prescription Drug Promotion and the CBER Office of Compliance and that an individual in each office be designated as the staff contact for biosimilars-related promotions.

### **Support Inter-Agency Tracking of Anti-Competitive Behavior**

LLS is concerned that brand companies, sometime acting alone and sometimes in cooperation with their generic or biosimilar competitors, engage in behaviors that delays the entry of competitive products into the biosimilars market. We strongly support the efforts of the FDA to be alert to such conduct and business arrangements and swiftly report any potentially anti-competitive activity to the FTC. Congress should support cooperation of the FDA and FTC to track anti-competitive behavior by requiring and fully funding collaborative efforts between the agencies to collect evidence of anti-competitive behavior with

respect to biosimilars. The agencies should consider creating and publicizing an easy-to-use portal that generic and biosimilar companies may use to report evidence of anti-competitive conduct and agreements directly to the FTC.

### **Improve the FDA's Purple Book**

While FDA has approved 17 biosimilars to date, the vast majority have not led to significant reductions in spending that many had assumed would follow their approval. One reason for the lack of biosimilar entry into the marketplace is the lack of detailed information provided in the Purple Book, the FDA's list of approved biologics and biosimilars, which is currently little more than an online spreadsheet of approved products. Most stakeholders, including physicians and manufacturers, are not even aware that it exists. As a result, many lack understanding of the clinical benefit of biosimilars and this has hindered development, acceptance and utilization. In contrast, the Orange Book, which includes information on generic drugs, is an authoritative resource due to the quality and quantity of the information it contains. The Orange Book has been refined over the decades to serve the needs of prescribers, dispensers, private and public payers, and those involved in coverage and formulary decisions. It also provides critically important patent, exclusivity, and product information for generic developers.

Congress should hold the FDA accountable for revising the Purple Book to more closely align with the Orange Book. The Purple Book should be made available as an online searchable database and not as a static spreadsheet, though it should also continue to be available in a fully downloadable format. Furthermore, the Purple Book should be greatly expanded to include, as the Orange Book does, an introduction of what it is and what it does, definitions of key terms and concepts, and establishment and explanation of use codes, abbreviations and acronyms. The Orange Book includes a very useful discussion titled "Statistical Criteria for Bioequivalence." LLS believes a similar section that explains what "biosimilar" and "interchangeable" mean from a scientific standpoint and what demonstrations FDA expects sponsors to make in order to receive these designations would be very informative for healthcare professionals and payers. This information would instill greater medical confidence in biosimilars and interchangeable products and the FDA decisions supporting them.

The Purple Book should also identify products that are discontinued on a table that is separate from currently approved or licensed products. The Purple Book should also align with the Orange Book and identify approvals by both product name and applicant name. Also, individual product entries in the Purple Book should align with the format used in the Orange Book, presenting the same information in the same style and include the established/proper name, proprietary name, dosage form, route of administration and strength, license number, date of licensure and designation of reference listed product status with the "+" symbol. Biosimilar and, eventually, interchangeable products, should be grouped with the reference product they reference and listed alphabetically by their shared International Non-Proprietary Name (INN). We also suggest that Congress encourage the FDA to consider adopting codes for biosimilarity and interchangeability that are similar to the ubiquitous "AB" status so widely used and understood for generic drugs. These biosimilarity and interchangeability ratings should be presented in a manner similar to that in the Orange Book, with a clear and obvious identification of the reference product.

### **Reform U.S. Biosimilar Naming Rules to Align with International Standards**

There continues to be confusion regarding the suffix that FDA has determined should be added to a biosimilar's International Non-Proprietary Name (INN). These suffixes do not align with World Health Organization (WHO) and European Union standards. Biosimilar acceptance might be slower in the U.S. than in the European Union in part because biosimilars in the U.S. must bear suffixes while those in the E.U. do not. Yet, it does not appear that the absence of suffixes on European biosimilars have, in any way, compromised patient safety. It may be that adding the suffix burdens U.S. biosimilars without any commensurate benefit for patients. Additionally, concerning recent reports that reference drug sponsors have implied that the reference listed product, without a suffix, is superior to the biosimilar with a suffix.

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Accordingly, Congress should require FDA to align federal biosimilar naming rules with international standards where possible, with particular focus on removing the current suffix requirement, given that it appears it may impose a burden upon U.S. biosimilars without advancing patient safety.

### **Reform Biosimilar Substitution & Interchangeability Rules**

Many attribute the slow market uptake of biosimilars to stakeholders' lack of familiarity and comfort with these products. The delay in market uptake can be compared to when generics first became available, although generic products are different in nature. Acceptance of small-molecule generics by physicians and payers took time, despite generics being chemically identical to the original brand-name products. The generics market has been enhanced over the years through strategies such as automatic substitution policies within pharmacies as well as through payer efforts. Given the fact that most biologics are covered under a patient's medical insurance benefit and are administered by physicians, the degree of retail-based pharmacy-level substitution may not prove to be as impactful as it has been for generic drugs. However, the interchangeability designation has the potential to significantly enhance provider and patient confidence in biosimilars, as more information about switching these particular therapies would be available as a result of the approval process.

Under the Biologics Price Competition and Innovation (BPCI) Act, an interchangeable biosimilar is defined as a biosimilar that is expected to produce the same clinical result as the reference product in any given patient. It may be substituted for the reference product without prescriber intervention, and the risk in terms of safety or efficacy of switching or alternating between biological products is no higher than using the reference product alone. The FDA released a draft guidance for biosimilar interchangeability in January 2017, and the final guidance is yet to be released. In order to be designated an interchangeable biosimilar, a product faces rigorous evaluation and must meet additional requirements based on further evaluation and testing. Therefore, a manufacturer would need to provide additional information to demonstrate that the biosimilar is expected to produce the same clinical result as the reference product in any given patient.

A biosimilar designated interchangeable is still the same molecule, but the difference is that there are more information and data available showing the impact of switching or alternating between the biosimilar and reference biologic.

- 1) Congress should hold the FDA accountable for finalizing its draft guidance on interchangeability of biosimilars and their reference products. We believe that finalizing the interchangeability guidance is a crucial part of achieving cost savings in the biological product market. This guidance will give the industry a clear, consistent framework to demonstrate interchangeability, which in turn will encourage manufacturers to invest in research and development of biosimilar products and to seek the designation of interchangeability for their products.

A recent report based on qualitative research with 10 medical directors at U.S. payer organizations highlighted findings that the interchangeability designation is playing a role in product management decisions.<sup>33</sup> The report noted that biologics are commonly utilized in patients with chronic conditions, and therefore switching drugs is typically only considered when treatment stops working or results in adverse events. Hence, there is hesitation to switch medically stable patients to biosimilars, even if costs are lower with a biosimilar. The report concluded that interchangeability can help drive formulary decisions and automatic substitution processes, and can also encourage payers to leverage policy to speed up adoption. A medical

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<sup>33</sup> Trinity Partners. (2018). The State of US Biosimilars Market Access: Payer Perceptions of Past, Present, and Future Hurdles to Adoption. Accessed at: [http://www.trinitypartners.com/files/5815/1638/4057/The\\_State\\_of\\_US\\_Biosimilars\\_Market\\_Access.pdf](http://www.trinitypartners.com/files/5815/1638/4057/The_State_of_US_Biosimilars_Market_Access.pdf)

director from a large national payer stated that they still expect biosimilars to capture half the market, “but only if there is steep discounting, or interchangeability status.”<sup>34</sup>

- 2) Congress should establish a federal standard for interchangeability and preempt state anti-substitution laws. While the FDA has not yet finalized guidance around interchangeability, state laws and regulations exist that place barriers on biosimilar adoption and access.<sup>35</sup> While currently none of the approved biosimilars in the U.S. are designated as interchangeable by the FDA, once this designation occurs, these varied state laws will be triggered.

A product approved as an interchangeable may be substituted for the reference product without the intervention of the healthcare provider who prescribed the reference product. Patients and healthcare professionals should be aware that once interchangeable biological products are available in the U.S., some states may permit an interchangeable product to be substituted for the reference product—a practice commonly called pharmacy-level substitution. Many states and state boards of pharmacy have passed laws or regulations that address the pharmacy-level substitution of products, and substitution laws and regulations may vary from state-to-state.

A clear and science-based federal standard regarding interchangeability that preempts state anti-substitution laws would lead to significant utilization of lower-cost biosimilars while stimulating the biosimilars marketplace into developing additional biosimilars.

LLS stands ready to work with you and your colleagues in Congress to advance the solutions we have outlined above and other proposals that would achieve savings without sacrificing patient access to appropriate cancer care. LLS’s executive leadership is available to meet and collaborate with you to achieve your cost reduction policy goals. Like you, we believe that we are at a crucial juncture in our healthcare system, and we urge Congress to capitalize on this real opportunity to make the reforms necessary to promote patient access to appropriate care while eliminating incentives that drive unnecessary spending. We are grateful for your leadership.

If you have any questions about our recommendations or other areas in which we can provide the patient perspective, please contact Brian Connell, LLS Executive Director of Federal Affairs, at [brian.connell@lls.org](mailto:brian.connell@lls.org). We look forward to working with you to make a positive difference for the patients, survivors, and caregivers we represent.

Sincerely,



Bernadette O'Donoghue  
Vice President  
Office of Public Policy

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<sup>34</sup> Ibid.

<sup>35</sup> National Conference of State Legislatures (2018) State Laws and legislation Related to Biologic Medications and Substitution of Biosimilars. Accessed at <http://www.ncsl.org/research/health/state-laws-and-legislation-related-to-biologic-medications-and-substitution-of-biosimilars.aspx>

Category	Issue	LLS Recommendation	Rec #
<b>Realign Incentives to Drive Down Costs</b>	Modernize risk-sharing mechanisms in Medicare Part D	Congress should restructure the Part D benefit design to reform the proportion of catastrophic benefit phase spending for which payers and the government are responsible. Rather than the government covering 80 percent of plan spending during the catastrophic phase of the Part D benefit, the program should require plans to cover 80 percent.	1
	Expand site-neutral payment in Medicare	Congress should require CMS to expand Medicare site-neutral payment policies. This has the potential to lower patient out-of-pocket costs and reduce unnecessary Medicare spending	2
	Reform Medicare Part B's 'buy-and-bill' system	Congress should hold the Centers for Medicare & Medicaid Services (CMS) accountable for testing various reforms that address perverse incentives in the 'buy-and-bill' system for prescription drugs provided under Medicare Part B. Given the critical role Part B plays in providing access to appropriate treatment for many cancer patients, reform proposals should begin as demonstration projects and expand based on robust and transparent review of the demonstration's results related to savings and patient outcomes.	3
	Bring transparency to drug pricing	Congress should require HHS should identify, within each drug class and for a given year, ten drugs in each of the following categories: (1) newly-approved branded drugs with the highest initial list price, (2) branded drugs with the highest increase in list price over the same period, and (3) generic and/or biosimilars drugs with the highest increase in list price, using a metric that most accurately reflects changes to cost burden relative to generic and biosimilar drugs. Each drug on this list should be identified publicly, and the manufacturer of each listed drug should be required to provide HHS a written justification drawing on the clinical and/or economic data that led to the highlighted prices and/or price changes.	4



<b>Avoid Wasteful Spending on Unnecessary Care</b>	Eliminate Medicare Spending on Drug Waste	Congress should pass the Recovering Excessive Funds for Unused and Needless Drugs (REFUND) Act (S. 551), which would curb Medicare Part B spending on the portion of the drug vial that is never given to the Medicare beneficiary. This reform will eliminate the existing profit incentive for drug manufacturers to produce drugs in packaging that guarantees substantial wasted product.	5
	Ensure Access to Optimal Treatment Planning	Congress should require federally-regulated insurance plans, including Medicare Advantage, to 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. Specifically, payers should establish a streamlined process to allow patients with cancer and other serious conditions to access specialty expertise from out-of-network providers, with patient cost-sharing identical to in-network care and counting toward the maximum out-of-pocket limits.	6
	Expand Access to Less-Costly Palliative Care	Congress should pass the Palliative Care and Hospice Education and Training Act, which would increase the availability and quality of palliative and hospice care that reduces costs to patients and the healthcare system.	7
<b>Empower Patients to Promote Value</b>	Promote patient decision-making with transparent cost information	Congress should require Part D plans to implement real-time benefit e-prescribing tools (RTBTs) that provide patients and prescribers with real-time information on a beneficiary's out-of-pocket liability for each of their treatment options.	8
	Facilitate competition through consumer-friendly plan transparency	1. Congress should require CMS to improve Medicare Plan Finder to convey important information on out-of-pocket drug costs so that consumers can judge their health care options based on complete information about the impact of their decision on their financial and physical health.	9

		2. Congress should require qualified health plans (QHPs) to provide transparency regarding the plan's prescription drug formulary, including meaningful cost-sharing information, to consumers during the open enrollment process. At a minimum, QHPs should be required to include for every covered drug a range of out-of-pocket spending for the prescription (e.g. \$\$\$\$\$ OR \$0-10, \$11-25...\$500+, etc.)	10
<b>Facilitate Value-Based Agreements (VBAs)</b>	Remove impediments to public & private VBAs	1. Congress should reform the Medicaid best-price regulations and anti-kickback regulations to allow contracting arrangements that include adjustments based on patient outcomes.	11
		2. Congress should hold CMS accountable for clarifying to the states the process by which a state can gain the flexibility necessary to experiment with innovative VBAs. Congress should require CMS to report to Congress each year on the impact of VBAs in state Medicaid programs in terms of both program savings and patient outcomes.	12
	Maximize value information for VBAs	Congress should require the GAO to study the most effective mechanism(s) for leveraging the FDA's post-approval requirement/commitment authorities to ensure that manufacturers provide timely information that can inform the understanding of drug's clinical costs and benefits following expedited approval.	13
<b>Eliminate Burdensome Cost-Sharing</b>	Cap Out-of-Pocket Costs in Medicare Part D	Congress should establish a monthly cap on out-of-pocket expenses in Medicare Part D. Such a cap would provide an important financial protection to Part D beneficiaries and would break down a barrier to treatment for the tens of thousands of seniors who are currently unable to obtain their cancer drugs due to cost.	14
	Share prescription drug rebates with patients	Congress should mandate a Part D rebate pass-through policy to help stem rising patient out-of-pocket costs by requiring a portion of the Part D rebates that manufacturers already pay to plans to be passed on to beneficiaries, reducing cost sharing for a given medication at the point-of-sale.	15

	Protect cancer patients from burdensome drug cost-sharing	Congress should pass the Cancer Drug Parity Act, which would ensure that patients experience the same cost-sharing for all cancer treatments, including oral therapies, regardless of how they are administered.	16
	Prevent surprise medical bills	Congress should establish a framework for surprise medical bills that ensures patients are held harmless in terms of cost-sharing for care unknowingly received by an out-of-network provider at an in-network facility or for emergency services received at an out-of-network facility.	17
<b>Promote Competition in the Rx Marketplace</b>	Ensure generic competitor access to product samples	Congress should pass legislation to prevent branded companies from using REMS ETASU processes to refuse to sell samples of their products to potential generic or biosimilar competitors.	18
	Promote Single Shared Systems (SSS) for REMS compliance	Congress should provide FDA sufficient resources to manage the process of encouraging the adoption of SSS REMS compliance while also approving waivers, where appropriate, to facilitate competition when competitors will not agree to a SSS.	19
	Prevent the patenting of REMS processes	1. Congress should require FDA to stop listing patents related to REMS methods or systems in the Agency's Orange Book and de-list such patents currently in the Orange Book.	20
		2. Congress should pass legislation deeming REMS methods or systems patents as within the "prior art," thereby limiting patent claims that branded companies have used to delay generic competition on REMS products.	21
	Prevent 'pay-for-delay' agreements	Congress should provide 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. Congress should pass legislation, such as the Preserve Access to Affordable Generics and Biosimilars Act (S. 64), which would strengthen the hand of the FTC in preventing brand pharmaceutical companies from compensating generic and biosimilar manufacturers to delay the market entry of generics and biosimilars competition.	22

	Prohibit shielding patents through tribal sovereign immunity	Congress should pass legislation, such as the Preserving Access to Cost Effective Drugs (PACED) Act (S. 440), to clarify that tribal sovereign immunity does not preclude patent review and enforcement by USPTO, federal courts, and the International Trade Commission.	23
	Explore patient-friendly remedies for 'product hopping'	Congress should investigate the issue of product hopping by requiring the GAO to study this practice and identify potential remedies or penalties for ending production of old formulation of drug without evidence of clinical benefit of new formulation.	24
	Prevent disinformation about biosimilars	1. Congress should encourage the FDA to exercise its authority under the Bad Ad Program, through sufficient appropriations and accountability measures.	25
		2. Congress should hold FDA accountable for its efforts to streamline the process for handling complaints regarding false/misleading promotions of biosimilars and provide sufficient funding for these efforts.	26
	Support inter-agency tracking of anti-competitive behavior	Congress should support cooperation of the FDA and FTC to track anti-competitive behavior by requiring and fully funding collaborative efforts between the agencies to collect evidence of anti-competitive behavior with respect to biosimilars.	27
	Improve the FDA's Purple Book	Congress should hold FDA accountable for revising the "Purple Book" to more closely align with the "Orange Book."	28
	Reform US biosimilar naming rules to align with international standards	Congress should require FDA to align federal biosimilar naming rules with international standards where possible, with particular focus on removing the current suffix requirement, given that it appears it may impose a burden upon U.S. biosimilars without advancing patient safety.	29
	Reform biosimilar substitution and interchangeability rules	1. Congress should hold the FDA accountable for finalizing its draft guidance on interchangeability of biosimilars and their reference products.	30
		2. Congress should establish a federal standard for interchangeability and preempt state anti-substitution laws.	31