LEUKEMIA & LYMPHOMA SOCIETY®
fighting blood cancers

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January 16, 2018

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

Re: Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program

Dear Administrator Verma:

The Leukemia and Lymphoma Society (LLS) appreciates the opportunity to comment on proposed changes to the Medicare Advantage (MA) and Medicare Prescription Drug Benefit programs, which deliver access to care for millions of Medicare beneficiaries, including those with blood cancer. LLS serves the needs of blood cancer patients by working to find cures for leukemia, lymphoma, Hodgkin's disease, and multiple myeloma, and by ensuring that blood cancer patients have sustainable access to quality, affordable, coordinated healthcare.

We are pleased to submit our comments on the proposed changes to Medicare Advantage (MA) and Part D; our feedback focuses on improvements to program quality, accessibility, and affordability—priorities that we believe are critical to improving the healthcare of our community.

In 2017, a third of Medicare beneficiaries received coverage through the MA program, rather than through Original Medicare—the proportion of beneficiaries in MA has doubled since the implementation of the Medicare Modernization Act in 2006.[1] Further, the Congressional Budget Office expects enrollment in MA to continue to increase over the coming years, reaching about 40% of Medicare enrollment nationwide by 2027.[2] Thus, changes to the MA program that increase program flexibility—but may increase confusion or limit affordability for enrollees—affect a substantial and growing proportion of the Medicare population, including beneficiaries with blood cancer, who rely on the program for access to care.

The last decade has also brought steady growth in Part D enrollment, providing important benefits for more than 40 million people with Medicare. However, benefit design trends in recent years have made treatment of blood cancer even less affordable for patients. The average percentage of covered drugs

[1] Kaiser Family Foundation. "Medicare Advantage 2017 Spotlight: Enrollment Market Update." https://www.kff.org/medicare/issue-brief/medicare-advantage-2017-spotlight-enrollment-market-update/
[2] Congressional Budget Office, "Medicare – Congressional Budget Office's January 2017 Baseline," January 24, 2017. Available at: https://www.cbo.gov/sites/default/files/recurringdata/51302-2017-01-medicare.pdf

that require coinsurance under standalone Part D plans has spiked from 35% in 2014 to 58% in 2016.[3] While Part D plans compete for enrollment by their premiums, the resulting changes to benefit design that must occur to keep premium increases minimal are leading to access concerns for many beneficiaries, including those who require high-cost therapies as a part of their care. And, while some of the changes proposed in this regulation may indeed increase the number of plans available to beneficiaries, the potential that these changes will reduce out-of-pocket costs might be more limited.

In addition to its stated focus on improving affordability, we also appreciate CMS' objective of enhancing beneficiaries' experience. However, while many of CMS' proposed changes could lead to more plan offerings and greater consumer choice, beneficiary experience and choice will only be meaningfully improved if consumers have the information and tools they need to differentiate between plan offerings. With this in mind, we have identified several opportunities for CMS to provide beneficiaries with information and other resources that will ensure that they are able take full advantage of new plan offerings and flexibility.

One of the core tenets of our Policy Recommendations for Reducing the Cost of Cancer Care[4] is to advance only those policy solutions that "offer meaningful improvements for patients." We look forward to collaborating with CMS and other stakeholders to deliver these meaningful improvements through greater affordability, flexibility, transparency, and the beneficiary experience in Medicare. We have seen too many major medical advances in recent decades to let "financial toxicity" prohibit patients from accessing life-changing treatments.

SELECT PART D COMMENTS

Request for Information Regarding the Application of Manufacturer Rebates and Pharmacy Price Concessions to Drug Prices at the Point of Sale

LLS strongly commends CMS' effort to design a policy that requires Part D sponsors to pass through a portion of manufacturer rebates and pharmacy price concessions to beneficiaries. As we stated in our Policy Recommendations for Reducing the Cost of Cancer Care, LLS supports policies that encourage rebates to be used to reduce costs at the point of sale.

Currently, rebates are used to benefit all other parties except the patient taking the medication. We understand that savings from manufacturer rebates may be applied to plans' or PBMs' operational activities or used to help lower premiums for all enrollees. However, premiums are not beneficiaries' only financial responsibility. In fact, patients who rely on Part D coverage to access expensive therapies who are most in need—such as those patients undergoing cancer treatment—are disproportionately burdened with other cost-sharing responsibilities, including often enormous drug coinsurance costs. We believe that establishing an appropriate rebate amount required to be passed

[3] Avalere Health. "Majority of Drugs Now Subject to Coinsurance in Medicare Part D Plans." http://avalere.com/expertise/managed-care/insights/majority-of-drugs-now-subject-to-coinsurance-in-medicare-part-d-plans
[4] Available at: https://www.lls.org/sites/default/files/National/Cost%20of%20Care%20LLS%20Recommendations%20-%20FINAL_Sept%202017.pdf.

onto consumers would be a significant step toward balancing cost-sharing responsibilities in a way that is sustainable for beneficiaries, plans, and manufacturers.

We encourage CMS to work with all stakeholders to continue to develop a specific, data-driven approach to determining average rebate amounts and specified minimum percentages to reduce negotiated prices for Part D covered drugs at the point of sale.

Implementation of the Comprehensive Addiction and Recovery Act of 2016 (CARA)

Beneficiaries Exempted from the Part D Drug Management Program

Ensuring that cancer patients with severe or prolonged pain have access to pain management therapies, including opioids, is critical for their care. For this reason, LLS applauds CMS for considering the cancer patient population and proposing appropriate exemptions from the drug management program. However, we caution that the proposed exempt population, qualified as an enrollee who "has a cancer diagnosis," might apply to a wide range of current or, even, former cancer patients who may not benefit from access to opioids, creating a potential loophole that could undermine the fundamental importance of CARA. We encourage CMS to carefully define this exempt group in a manner that reflects the nuance present in the cancer patient population. For example, an enrollee with a pediatric cancer diagnosis, now 20 years in complete remission, likely has drastically different pain management requirements than other enrollees with a cancer diagnosis who are undergoing treatment. Without a clear approach to defining who has a cancer diagnosis, this program could exempt beneficiaries who ought to be included in drug management efforts.

Notices to Beneficiaries of Drug Management Program

LLS supports CMS' implementation of CARA to help curb drug misuse and abuse. However, we encourage CMS to consider additional communication protocols for the program, to ensure enrollees understand impending limited access to certain drug coverage. Sending just two written notifications may run the risk of not reaching some enrollees, particularly because the notification does not require acknowledgement of receipt from the enrollee.

LLS suggests CMS consider additional protocols to contact enrollees who may be unreachable via written notification. These may include contact from the prescribing physician, a phone call, or a required confirmation of receipt from the enrollee. LLS also urges CMS to ensure appropriate readability of notices for the Medicare population by testing communications in focus groups or similar settings.

Treatment of Follow-On Biological Products as Generics for Non-LIS Catastrophic & LIS Cost-Sharing

Biosimilar products have the potential to reduce costs for patients and the healthcare system. LLS applauds CMS' proposal to realize these potential cost savings by revising the definition of generic drugs to include follow-on biological products for purposes of non-low-income subsidy (LIS) catastrophic cost sharing and LIS cost sharing. We believe that the implementation of this proposal will increase affordability of life-saving treatments and reduce overall healthcare system costs by incentivizing the use of lower-cost alternatives

Part D Tiering Exceptions

LLS strongly commends CMS for discussing the value of tiering exceptions and clarifying the requirements for granting tiering exceptions. This clarification is imperative, as the current rules on tiering exceptions are ambiguous and may be interpreted in different ways. Tiering exceptions can be extremely beneficial to patients by allowing them, based on clinical need, to access a non-preferred drug with the lowest cost-sharing on the preferred tier. However, LLS has two distinct comments to the approach CMS took to clarify this policy.

First, if a patient requires a drug on the specialty tier—where many cancer treatments are placed—CMS rules prohibit his or her access to a tiering exception resulting in patients facing, typically, 33% coinsurance. Furthermore, patients who are taking drugs on a specialty tier often do not have alternate options available to them on a preferred tier. For cancer patients who are likely taking multiple drugs, including multiple specialty drugs, the lack of an appropriate tiering exception can result in very high out-of-pocket costs each year. Such high costs too often decrease adherence to life-saving therapies, limiting the value of Part D coverage for cancer patients and many other beneficiaries. LLS urges CMS to revise this proposed rule to include an expansion of the Part D cost-sharing tiering exception to include drugs placed on a plan's specialty tier.

Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes

LLS supports measures that minimize barriers to access for generic medications. CMS' proposal to allow generic substitutions immediately when such drugs come to market does just that, by preventing a potential delay in access while patients wait for direct notice or a formulary change request. However, the proposed rule also allows for plans to offer general, non-specific notice that these changes might occur.

Since the approval of therapeutically equivalent generics is known by plans well in advance of release of these products, LLS believes that plans should continue to deliver beneficiary-targeted, specific notices to affected individuals 30 days in advance of such formulary changes. Beneficiaries who are unaware that a new generic of their medication is available may be confused and, potentially, discontinue treatment, upon discovering their newly filled medication has a different name, color, or shape than they expect. The general notice proposed by CMS may not offer sufficient warning for beneficiaries to recognize that the change in their medication is appropriate.

Eliminating the Requirement to Provide PDP Enhanced Alternative (EA) to EA Plan Offerings with Meaningful Differences

LLS supports CMS' intent to eliminate the "meaningful difference" requirement on EA benefit designs offered by the same organization in the same region, because, as CMS notes, it could drive down average supplemental Part D premiums and lead to increased numbers of plans offered.
However, for many beneficiaries, choosing a PDP from among the many options on offer can be challenging. With the elimination of the meaningful different requirement—and the corresponding potential for increased numbers of plans—CMS must ensure its tools to help beneficiaries find plans that best meets their needs offer details on the enhancement offered by all enhanced plans. Specifically, CMS should update the Plan Finder and the Medicare and You handbook to include a notation about the method(s) of enhancement used by all enhanced plans. Further, the Plan Finder also should allow

beneficiaries to filter and/or sort plans by these enhanced features. For CMS to ensure that beneficiaries can make the most of the innovative options potentially being offered with this new policy, plan selection tools must reflect the ways in which these plans might be distinguished from one another. Finally, we also encourage CMS to collect ongoing feedback from beneficiaries, to monitor any issues, and to improve the usability and customer experience of Plan Finder based on these data.

SELECT PART C COMMENTS

Flexibility in the Medicare Advantage Uniformity Requirements

LLS agrees that disease-tailored benefit design could benefit patients with chronic and/or complex conditions, as they often have unique and reoccurring healthcare needs. These beneficiaries, including cancer patients, may gain from plans designed to reduce cost-sharing for services they frequently require. However, it is essential that CMS ensure that allowing increased flexibility to tailor benefit design does not become a guise for discrimination toward higher-cost enrollees.

We are concerned that flexibility in uniformity requirements could result in higher cost-sharing for certain benefits, and suggest that CMS put in place strong anti-discrimination tests for the new disease-tailored benefit designs. We understand that CMS is planning to review benefit designs; we appreciate this intent, and urge CMS to evaluate plans before they are offered to beneficiaries, as well as on a continual basis, and make the test results available to the public.

In addition to anti-discriminatory tests, we encourage CMS to clearly present differences in plan types to consumers, so they can make informed decisions. We urge CMS to clearly designate in Plan Finder and the Medicare and You Handbook which benefits have adjusted and how. CMS may also consider building a more effective cost-calculator tool that helps beneficiaries estimate their yearly costs and allows for comparison across plans.

Meaningful Differences in Medicare Advantage Bid Submissions and Bid Review

Similar to our comments for Part D plans, LLS also supports eliminating the meaningful difference requirement for MA plans, so long as CMS equips customers with the education and tools they need to understand and compare plans. As we discussed above, eliminating the requirement may lead to an abundance of similar plans that are difficult for beneficiaries to distinguish. CMS must mitigate this risk by advancing the Plan Finder technology to help beneficiaries make an informed decision about their coverage.

We urge CMS to invest in consumer education programs and upgraded Plan Finder technology to ensure beneficiaries are equipped with resources that can help them distinguish plans and find options to meet their needs.

Maximum Out-Of-Pocket Limit for Medicare Parts A and B Services

LLS supports CMS' efforts to encourage plans that offer reduced maximum out-of-pocket (MOOP) limits. This effort could improve healthcare affordability for blood cancer patients, many of whom pay thousands of dollars in out-of-pocket costs to access their needed care.

For beneficiaries across the spectrum of healthcare needs to fully benefit from a policy that encourages plans with a range of MOOP limits and corresponding differences in cost sharing, CMS must help beneficiaries sort through their options in a more effective method than the current tools offer. Specifically, CMS should update the Plan Finder and Medicare and You to guide beneficiaries through the process of choosing an MA plan, including more precise, accurate, and modifiable calculations of expected out-of-pocket costs. Updated tools can help beneficiaries understand whether they will benefit more from a plan with a reduced MOOP or whether a plan with lower cost sharing meets their needs more effectively.

About LLS

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

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

Sincerely,
Bernadette O'Donoghue
Vice President, Public Policy