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February 19, 2019

Alex M. Azar, II
Secretary
Department of Health and Human Services
200 Independence Ave., SW
Washington, DC 20201

Seema Verma
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: CMS-9926-P – Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2020
84 Fed. Reg. 227 (January 24, 2019)

Dear Secretary Azar and Administrator Verma:

The American Cancer Society Cancer Action Network (ACS CAN), appreciates the opportunity to comment on the 2020 Notice of Benefit and Payment Parameters proposed rule. ACS CAN, the nonprofit, nonpartisan advocacy affiliate of the American Cancer Society, supports evidence-based policy and legislative solutions designed to eliminate cancer as a major health problem. ACS CAN empowers advocates across the country to make their voices heard and influence evidence-based public policy change as well as legislative and regulatory solutions that will reduce the cancer burden.

I. EXECUTIVE SUMMARY

Currently, enrollees in federally-facilitated exchanges who do not choose a new plan for themselves at the start of a new benefit year are automatically re-enrolled into the same or similar plan for the following year, based on a re-enrollment hierarchy established in previous regulation. According to HHS, "in the open enrollment period for 2019 coverage, 1.8 million people in states using the Federal platform were automatically re-enrolled in coverage… Automatic re-enrollment significantly reduces issuer administrative expenses and makes enrolling in health insurance more convenient for the consumer."[1] Despite this, HHS expresses concerns and seeks comments on the automatic re-enrollment processes as well as "additional policies or program measures that would reduce eligibility errors and potential government misspending for potential action in future rulemaking applicable not sooner than plan year 2021."[2]

ACS CAN supports giving consumers the option of being automatically re-enrolled in their plan in subsequent years if their plan and/or their personal circumstances do not change. Keeping consumers insured and making it easier for them to re-enroll are important goals that prevent consumers from having coverage gaps. Any gap in coverage can be especially problematic for cancer patients and survivors. Uninsured Americans are less likely to get screened for cancer, more likely to be diagnosed with cancer at an advanced stage, and less likely to survive that diagnosis than those with insurance.

[1] 84 Fed. Reg. at 229.
[2] Id.

Conversely, individuals with health insurance are about twice as likely as those without it to have access to critical early detection cancer procedures.[3]

Evidence-based protocols for chemotherapy and other cancer therapies often require that treatments be administered on a prescribed timeline. Gaps in coverage may interrupt treatment schedules which could jeopardize outcomes. A gap in coverage can also delay initiation of treatment which could adversely affect outcomes. For example, research shows that delays in the initiation of chemotherapy for breast cancer patients result in adverse health outcomes.[4] Even gaps in coverage for a few years during young adulthood mean missing important cancer screenings and prevention – like the HPV vaccine, which must be administered by age 26.

We urge HHS to maintain its automatic re-enrollment policy in the federally-facilitated exchange.

II. PROVISIONS OF THE PROPOSED HHS NOTICE OF BENEFIT AND PAYMENT PARAMETERS FOR 2020

B. Part 147 – Health Insurance Reform Requirements for the Group and Individual Health Insurance Markets

Under existing rules guaranteeing the availability of coverage, issuers are prohibited from modifying health insurance coverage mid-year except under limited circumstances where the modification is considered a uniform modification. Otherwise changes to individual and group health insurance plans must be made at coverage renewal.

HHS proposes permitting issuers to make mid-year formulary changes when a generic equivalent of a prescription drug becomes available. Under the provision, a plan would be permitted to add the new generic and remove the equivalent brand drug from its formulary or move the brand drug to a different cost-sharing tier on the formulary. For an issuer to take advantage of this mid-year modification, it must notify plan enrollees in writing at least 60 days before making the change and all enrollees must have access to the coverage appeals process and the drug exception request process.

ACS CAN supports increasing access to and encouraging the use of generic drugs, as one way to address the complicated problem of rising prescription drug costs for plans and patients. Allowing issuers to add generic drugs to their formularies mid-year is an appropriate policy change for HHS to make.

However, we encourage HHS to modify this proposal to prohibit issuers from removing the branded drug entirely from their formularies, move the branded drug to a higher tier, or assign higher cost-sharing for the branded drug mid-year. For certain patients, the generic alternative might be contra-indicated, and they may need to stay on the branded drug.

These patients may have chosen their plan specifically because of coverage of and/or formulary placement of the branded drug they knew they needed to take. Allowing issuers to make changes to coverage of this drug is unfair to patients and could result in significantly increased costs, delays in treatment, and/or worse health outcomes for cancer patients who are unable to take the generic equivalent. We are also concerned that some patients may not receive the required notice 60 days

[3] Ward E, Halpern M, Schrag N, Cokkinides V, et al. Association of Insurance with Cancer Care Utilization and Outcomes. CA: A Cancer Journal for Clinicians, 2008;58: 9–31. doi:10.3322/CA.2007.0011.
[4] Chavez-MacGregor M, Clarke CA, Lichtensztajn DY, Giordano SH. Delayed Initiation of Adjuvant Chemotherapy Among Patients With Breast Cancer. *JAMA Oncol.* 2016;2(3):322-329. doi:10.1001/jamaoncol.2015.3856.

before the change or may not be capable of understanding the notice. ACS CAN hears anecdotally that it is common for cancer patients to ignore their mail during the most grueling parts of treatment, which may cause them to miss contact attempts under this policy. This could result in confusion at the pharmacy counter (at best), and large, unexpected cost-sharing amounts at the pharmacy counter (at worst).

D. Part 155 – Exchange Establishment Standards and Other Related Standards

2. General Functions of an Exchange

b. Navigator Program Standards

Under current law, each Exchange is required to have a Navigator program with staff trained to assist consumers with enrolling in QHPs and other insurance programs for which they may be eligible. In past rules, HHS has added other topics to required navigator training, such as (1) filing Exchange eligibility appeals; (2) understanding and applying for exemptions to the shared responsibility payment; (3) understanding the premium tax credit reconciliation process and IRS resources; and, (4) understanding basic health coverage concepts and how to use health coverage. HHS proposes to remove Navigator training requirements for these additional topics, and only retain requirements for core navigator functions for plan year 2020.

While HHS cites the desire to give navigator programs more "flexibility" as the reason for this change in training requirements, ACS CAN notes that this change comes at a time when the Administration has drastically cut funding to these navigator programs for the second year in a row.[5] ACS CAN strongly opposes these funding cuts and urges the Administration to restore full funding for outreach and enrollment. This funding is vital in ensuring a robust marketplace and access to quality health coverage for cancer patients and survivors. Rather than reducing training requirements, we strongly urge HHS to restore funding so navigator programs can continue to help consumers on the range of topics for which they need help – including the topics HHS proposes to no longer require.

3. Exchange Functions in the Individual Market: Enrollment in Qualified Health Plans

b. Special Enrollment Periods (§ 155.605)

HHS proposes to allow Exchanges the option to provide for a new special enrollment period (SEP) for individuals enrolled in non-Exchange plans in the individual market to enroll in an Exchange plan if they experience a decrease in household income and receive a new determination of eligibility for a premium tax credit by an Exchange.

ACS CAN supports inclusion of this new SEP. Eligibility for subsidies is an important factor in the choices many consumers make when enrolling in health insurance. It is likely that some consumers, upon learning they are not eligible for subsidies, choose a plan with less generous coverage because the premiums are more affordable. Such an individual may have been just above the subsidy-eligible income level, and if that individual has a change in their income and became subsidy-eligible, they might want to choose a plan with more generous coverage. This SEP will allow this individual to, for example, move

[5] Keith, Katie. "CMS Announces Even Deeper Navigator Cuts." Health Affairs Blog. July 12, 2018. https://www.healthaffairs.org/do/10.1377/hblog20180712.527570/full/.

from a bronze plan – which was all they could afford at the time – to a silver or gold plan with a subsidy. Patients diagnosed with cancer frequently experience an unexpected loss of annual income, as many cancer patients have to reduce their work hours while they are receiving treatment and/or into survivorship.[6] This SEP could allow cancer patients and survivors to buy more generous coverage once they become eligible for subsidies.

Currently several SEPs available in the marketplaces require consumers to prove they had prior coverage. HHS proposes to add to the types of coverage that can be considered prior coverage for the purpose of satisfying a prior coverage requirement to include Medicaid on the basis of pregnancy, Medicaid medically needy, and CHIP unborn child coverage.

ACS CAN supports these changes. These categories of Medicaid and CHIP coverage provide access to health care to low-income individuals, and it is unlikely that these individuals would be able to afford having an additional source of health insurance coverage. These individuals should not be disadvantaged by this fact when applying for coverage through the marketplaces.

E. Part 156 – Health Insurance Issuer Standards Under the ACA, Including Standards Related to Exchanges

2. Silver Loading

Section 1402 of the ACA requires issuers to provide cost-sharing reduction subsidies (CSRs) to individuals whose income is below 250 percent of the federal poverty level and who choose to enroll in a silver level marketplace plan. The ACA also requires HHS to reimburse issuers for the CSRs, which had occurred until October 2017 when, as noted in the preamble, HHS directed CMS to discontinue payments to issuers for CSRs until Congress appropriated funds. In response, a majority of states allowed issuers to increase premiums only on silver-level plans to make up for the lack of CSR funding (a practice that is commonly referred to as "silver loading") without raising premiums across the board. HHS does not propose any specific changes, but rather seeks comment on ways HHS might address silver loading.

ACS CAN appreciates HHS' solicitation of stakeholder comments on this important issue. Premium tax credits are calculated based on the second lowest-cost silver level plan and thus silver loading has resulted in eligible enrollees receiving a higher premium tax credit. This higher tax credit allows eligible enrollees the opportunity to purchase bronze- or gold-level coverage for a lower premium. However, at the same time, individuals who do not qualify for tax credits are facing higher silver-level premiums as a result of silver-loading.

We have long advocated for the need for permanent CSR funding. We urge HHS to refrain from changing any policies that would impact silver loading until such time as permanent, stable CSR funding is provided to issuers. Making adjustments to silver-loading before such funding is provided increases the likelihood of uncertainty in the individual market and could cause market disruptions that could further destabilize these markets, which could result in even higher overall premiums.

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[6] Moran JR, Short PF, Hollenbeak CS. Long-Term Employment Effects of Surviving Cancer. J Health Econ. 2011 May; 30(3): 505–514.

After permanent and stable funding is provided, we recognize that silver-loading would no longer be necessary, given that the policy was created in response to the lack of CSR funding. However, we also recognize that banning and/or limiting silver-loading could result in significant out-of-pocket costs for eligible enrollees who would see the amount of their premium tax credit reduced. Thus, we would urge HHS to mitigate the impact by phasing in a limitation on silver-loading over time so that eligible enrollees are not exposed to significant premium spikes as this policy is corrected.

3. Essential Health Benefit Package

a. State selection of EHB-benchmark plan (§ 156.111 and § 156.115)

In previous regulations[7] HHS gave states more flexibility in selecting an Essential Health Benefits (EHB) benchmark beginning in plan year 2020. In the current proposed rule, HHS establishes deadlines for states to officially submit their benchmark selections for plan years 2021 and 2022. HHS also notes that it believes the third new benchmark option, selecting a set of benefits for the state's benchmark, provides opportunities for states to address the opioid epidemic.

ACS CAN opposed the changes HHS made to the benchmark selection process in the 2019 payment rule[8] because we believe they could result in states choosing a less generous coverage standard that is not based on an actual plan sold in the state.

We acknowledge the need for states to address the opioid crisis and would be supportive of states using their EHB benchmark to require more generous coverage of opioid reversal agents, non-opioid or non-addictive pain medications, and/or non-drug pain treatments. However, we strongly caution HHS that states may use this additional "flexibility" and this reasoning to cut drugs from its EHB benchmark and establish a benchmark that prevents patients from accessing medications they need to treat disease or maintain their quality of life. We note that the state of Alabama used this flexibility to propose drastically cutting its EHB drug benchmark, including cutting opioids, non-opioid pain treatments, and even treatments for opioid use disorder – as well as drugs not at all related to the opioid epidemic.[9] The result of these types of proposed changes is of great concern for access to drug therapies for cancer patients. We caution states and HHS that drastically cutting coverage of all opioid treatments is not the best way to address opioid misuse by a segment of the population. Those with serious illness and nearing the end-of-life often need access to these drugs for legitimate pain and other symptom relief. While Alabama eventually withdrew its proposal, we caution HHS in encouraging similar proposals in the future.

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[7] Department of Health and Human Services. Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2019. 83. Fed. Reg. 16930 (Apr. 17, 2018).
[8] American Cancer Society Cancer Action Network. Comments on 2019 HHS Notice of Benefit and Payment Parameters Proposed Rule, Nov. 27, 2017, available at https://www.fightcancer.org/sites/default/files/ACS%20CAN%20Comments%202019%20NBPP%20FINAL.pdf.
[9] American Cancer Society Cancer Action Network. Comments on Alabama PY2020 EHB Benchmark Plan Revisions, August 3, 2018, available at https://www.fightcancer.org/sites/default/files/ACS%20CAN%20Comments%20on%20AL%20EHB%20Drug%20Proposal%208-3-18%20Final.pdf.

We do note that HHS reminds states that they "must have completed the required public comment period and submit a complete application by the deadlines."[10] We urge HHS to strictly enforce this requirement, as past state examples showed that states were not committed to robust public comment periods. We urge HHS to reject any application that was not the result of a robust public comment period at the state level.

b. Prescription drug benefits (§ 156.122)

HHS is soliciting comments on two prescription drug policies. First, HHS is soliciting comment on whether therapeutic substitution and generic substitution policies should be pursued. Second, HHS seeks comment on the opportunities and risks of implementing and incentivizing reference-based pricing for prescription drugs. The preamble defines reference pricing as occurring "when an insurer in a commercial market covers a group of similar drugs, such as within the same therapeutic class, up to a set price, with the enrollee paying the difference in cost if the enrollee desires a drug that exceeds the set (reference) price."[11]

Therapeutic substitution and generic substitution: ACS CAN supports the use of therapeutic alternatives and generic drugs, when medically appropriate for individuals. However, we note that in cancer care, prescription drug regimens may not allow for the use of alternative drugs, even within the same class or subclass. For example, molecular target inhibitors are used to treat a variety of different cancers harboring specific genetic mutations. Many of these drugs are relevant to a small subcategory of patients within a single disease and are not necessarily interchangeable products.

To the extent that HHS proceeds with a proposal to encourage therapeutic substitution and/or generic substitution, we strongly urge that the proposal contain policies that provide an exceptions process so that individuals who have a medical need for a specific drug are able to access that drug in a timely manner. In addition, HHS should proceed with caution in implementing such policies so as not to disrupt patient medication compliance. Prescription drug noncompliance can lead to poorer health outcomes for enrollees and increased health care costs.

Reference-based pricing: ACS CAN is concerned with HHS' consideration of reference-based pricing as described in the preamble. We note that the article referenced in the preamble in support of the idea of reference-based pricing, includes some noteworthy limitations.[12] For example, the authors noted that they "could not assess whether the changes in the selection exerted any effect on adherence to medication therapy for individual employees or their health outcomes."[13] Also, the outcomes data analyzed were limited solely to prescription drug utilization, and thus the authors were unable to determine whether there were any increases in non-pharmaceutical services. Finally, the authors cautioned that "[f]uture evaluations of reference pricing will need to assess health outcomes, especially if reference pricing is extended to complex specialty drugs."[14]

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[10] 84 Fed. Reg. at 283-284.
[11] 84 Fed. Reg. at 284.
[12] Robinson, J.C, Whaley, C.M., & Brown, T.T. (2017). Association of Reference Pricing with Drug Selection and Spending. New England Journal of Medicine, 377:658665. Doi:10.1065/ NEJMsa1700087.
[13] Id.
[14] Id.

As noted above, we support the use of lower-cost alternative therapies where appropriate. However, cancer care is often specialized and thus not appropriate for reference-based pricing. As an example, both Gefitinib and Crizotinib are approved by the Food and Drug Administration (FDA) to treat lung cancers with specific genetic mutations. However, Gefitinib is used to treat EGFR mutant lung cancers and Crizotinib is approved to treat ALK mutant lung cancers. Even though these drugs are used to treat the same disease (lung cancer) and both drugs are included in the molecular target inhibitor category, their FDA indication is unique to a specific genetic subtype of lung cancer and as such these drugs are not necessarily interchangeable products. It would not be appropriate to include them in the same category for reference pricing.

Before HHS proceeds with any reference-based pricing policy that is similar to that outlined in the preamble, we would strongly encourage that it conduct additional research to determine the potential impact on non-pharmaceutical services. We are concerned that, to the extent such a policy would reduce utilization of certain prescription drugs, it might cause an increase in utilization of other medical services because patients are not getting treatments they need and having worse health outcomes. In addition, HHS should also examine the appropriateness of such policy on specialty drugs, including cancer care. Finally, we note that depending on how such policy is implemented, it could conflict with current anti-discrimination policies like ACA section 1557 which prohibits a benefit design from discriminating against an enrollee on the basis of her medical condition, among other factors.

d. Premium adjustment percentage (§ 156.130)

ACA section 1302(c) directs the Secretary to determine the annual premium adjustment percentage, which is used to calculate the maximum out-of-pocket limit, the employer mandate penalty, and eligibility for certain individual mandate penalty exceptions. HHS is proposing to use an alternative premium measure, which would use average per enrollee private health insurance premiums (excluding Medigap and property and casualty insurance) rather than the current measure which uses employer-sponsored insurance premiums.

ACS CAN is concerned with the potential impact of this proposal and urges HHS to withdraw its proposal given the negative impact on enrollees, as discussed in more detail below:

Increased premiums and lower enrollment: According to HHS' own regulatory impact analysis, this policy would result in net premium increases to those who receive tax credits of $181 million per year, which is one percent of the 2018 benefit year net premiums.[15] These premium increases would impact individuals in both state-based and the federally-facilitated marketplace. According to one analysis, at least 7.3 million Americans would be impacted and would have to pay higher premiums.[16] The amount of the premium increase would vary but could be hundreds of dollars a year.[17] These increases would affect low-income enrollees who are likely to find larger premium payments very challenging to absorb into their already tight budgets. We are concerned that increased premiums could cause people to

[15] 84 Fed. Reg. at 308.
[16] Aviva Aron-Dine and Matt Broaddus. "Change to Insurance Payment Formulas Would Raise Costs for Millions With Marketplace or Employer Plans." Center on Budget and Policy Priorities. Jan. 18, 2019, available at https://www.cbpp.org/sites/default/files/atoms/files/1-18-19health.pdf.
[17] Id.

forego coverage, or choose an off-Marketplace plan, which may not provide comprehensive benefits. In fact, HHS estimates that enrollment in marketplace plans would be reduced by 100,000 individuals in the year 2020, and enrollment would remain lower by 100,000 individuals in each year between 2020 and 2023.[18]

Cumulatively the proposed policy would not only impact subsidy-eligible individuals but could result in higher premiums for individuals who do not qualify for subsidies. As the preamble notes, "the proposed change could also contribute to a decline in Exchange enrollment among premium tax credit eligible consumers, and could ultimately result in net premium increases for enrollees that remain in the individual market, both on and off the Exchanges, as healthier enrollees elect not to purchase Exchange coverage."[19] We are concerned this policy could contribute to a destabilization of the Marketplace and result in fewer Americans choosing comprehensive coverage options. We urge HHS to withdraw this proposed policy.

Higher out-of-pocket costs in all private insurance: In addition, this change would result in a higher maximum out-of-pocket limit for all non-grandfathered private insurance plans, including those enrolled in employer-sponsored insurance. The preamble notes the maximum out-of-pocket limit would increase $200, to $8,200 in 2020 and $400 for individuals with family coverage (up to $16,400 in 2020). This represents a 3.8 percent increase. While the one-year increase may seem minimal, we are concerned about the cumulative impact of this policy, which will result in enrollees not only paying more in premiums but also will have to spend more before hitting their maximum out-of-pocket cap. ACS CAN's Costs of Cancer report showed that typical cancer patients in the individual market reach their maximum out-of-pocket limit in the first 1-3 months after a positive cancer screening – meaning they must pay multiple thousands of dollars in a very short amount of time.[20] Allowing this maximum limit to increase will mean newly-diagnosed cancer patients – and many survivors – will have to pay more out-of-pocket costs.

g. Application to Cost-Sharing requirements and annual and lifetime dollar limitations (§ 156.130)

HHS is proposing several policy changes to cost-sharing requirements, including what is included under the Essential Health Benefit (EHB) standards, which impacts the annual and lifetime dollar limitations.

i. cost-sharing requirements for generic drugs

HHS is proposing to allow a plan that covers both a brand prescription drug and its generic equivalent to consider the brand drug not to be an Essential Health Benefit if the generic drug is available and medically appropriate for the enrollee, unless coverage of the brand drug is required under the exceptions process. Under the proposal, if an enrollee were to purchase the brand drug when the generic equivalent was available and medically appropriate, the issuer would be permitted to not count the difference in cost sharing between the brand drug and its generic equivalent toward the annual limit on cost-sharing. Instead, the issuer would only count the cost of the generic equivalent toward the

[18] 84 Fed. Reg. at 308.
[19] 84 Fed. Reg. at 287.
[20] American Cancer Society Cancer Action Network. The Costs of Cancer: Addressing Patient Costs. April 2017. Available at www.fightcancer.org/costsofcancer.

annual out-of-pocket limit. HHS also suggests an alternate proposal that would allow the issuer to except the entire amount paid for a brand drug when there is a medically appropriate generic version available.

ACS CAN has serious concerns with this proposal and strongly urges HHS not to finalize the policy. We are concerned that this policy would allow an issuer to offer a plan that provides limited coverage of branded products (in fact, only offer coverage of branded products when a generic equivalent is not available). ACS CAN supports the encouragement of enrollees to utilize lower-cost generic drugs, where medically appropriate to do so. However, we note that in cancer care, prescription drug regimens may not allow for the use of alternative drugs.

Impact on annual and lifetime limits: As noted in the preamble, the ACA's prohibition on annual and lifetime limits only pertains to EHB-covered services. Thus, under the proposal, an issuer could impose a lifetime and/or annual limit on branded prescriptions drugs. To the extent plans are permitted to impose coverage limitations on medically appropriate therapies, it will likely have a negative impact on enrollees' medication adherence. Prescription drug noncompliance can lead to poorer health outcomes for the enrollee.

Exceptions process would be overwhelmed: We note that the proposed rule would allow an enrollee to utilize the exceptions process, however we are concerned that this policy does not provide an adequate safeguard to assure that individuals have access to medically appropriate therapies. As an initial matter, we are concerned that the exceptions process could easily be overwhelmed – particularly at the beginning of a plan year – which would likely impede the plan's ability to adhere to the timeframe under which a plan must decide on an exceptions request.[21] We also note that this policy will impose a significant burden on providers.

Would make plan selection difficult: The proposed policy would also make it challenging for an enrollee who is shopping for a health plan. Prospective enrollees may not be made aware of the fact that a plan doesn't cover any branded prescription drugs, and that the enrollee would have to go through the exceptions process in order to determine whether the plan would provide coverage. While issuers will have to inform enrollees of this new policy, we are concerned that such information may not be prominently displayed to enrollees and thus they may not be aware of the new policy until they go to fill a branded prescription drug and incur a high surprise bill as a result.

In addition, we note that individuals are not able to utilize the exceptions process on a prospective basis, and thus the enrollee will have no way of knowing until after they enroll in a plan. If the enrollee's exceptions request is denied, absent a change in circumstances, the enrollee will not qualify for a special enrollment period that would allow them to enroll in another plan (assuming the option existed) and must remain covered under their current plan.

Anti-discrimination concerns raised: This policy runs counter not only to the intent of the ACA's important consumer protections, but conflicts with current anti-discrimination policies like ACA's section

[21] 45 C.F.R. § 165.122(c) requires health plans to make a determination on a standard exception no later than 72 hours following the receipt of the request and an expedited exception no later than 24 hours following the receipt of the request.

1557 which prohibits a benefit design from discriminating against an enrollee on the basis of her medical condition, among other factors. Additionally, if most or all issuers engaged in such practices, individuals with serious or chronic illness would be left with few or no plans to choose from that actually cover the services they need.

Does not protect enrollees from high out-of-pocket costs: While the proposal only permits plans to have this type of policy on branded drugs that have covered generic equivalents, the proposal does not require these covered generic equivalents to be placed on a particular formulary tier or limit cost sharing for these drugs. Presumably, a plan would be permitted to create a new formulary tier of generic drugs with branded alternatives and charge high copays or coinsurance for these drugs.

The alternative approach is worse: As discussed above, we have strong concerns with the initial proposal and would strongly urge HHS not proceed with the alternative approach, which would be even more harmful to consumers because it doesn't even provide an exception for medical necessity. We believe such a policy would harm beneficiaries with serious illness and run afoul with the ACA's anti-discrimination provisions.

ii. cost-sharing requirements and drug manufacturers' coupons

HHS proposes that amounts paid toward an enrollee's cost sharing using any form of direct support offered by drug manufacturers to insured patients in order to reduce or eliminate their out-of-pocket costs would not be counted toward the enrollee's annual maximum out-of-pocket costs. This policy would only apply in cases where the manufacturer's support is provided to a brand drug for which there is a generic equivalent.

ACS CAN supports the use of copay assistance programs because many individuals would otherwise be unable to afford the cost sharing associated with their prescription drugs. HHS notes this same reasoning in the preamble: "We recognize that copayment support may help beneficiaries by encouraging adherence to existing medication regimens, particularly when copayments may be unaffordable to many patients."[22]

We are concerned that the proposal would make branded drugs completely unaffordable for certain cancer patients. ACS CAN does not support limitations on the use of copay assistance programs (including whether these funds will count towards the individual's maximum out-of-pocket cap) unless (1) the prohibition is limited to instances when a true therapeutic alternative exists and is covered by the formulary and (2) when medical allowances are made for individuals for whom the generic drug is contra-indicated. We note that the proposal only speaks to whether a generic equivalent of the branded prescription exists, but the proposal does not require the plan to provide coverage for the generic product. If HHS were to finalize this policy, we urge the inclusion of the requirement that plans must cover the therapeutically equivalent generic drug. Also, while generic drug utilization can, and should, be encouraged, we note that it may not be appropriate in all instances. Some individuals are unable to take a generic product because it could be contra-indicated (for example, if the individual is allergic to the inert ingredients contained in the generic drug). If HHS were to finalize this policy, we urge the inclusion of provisions that would make allowances for medical necessity.

[22] 84 Fed. Reg. at 290.

CONCLUSION

Thank you for the opportunity to comment on the 2020 Notice of Benefit and Payment Parameters proposed rule. If you have any questions, please feel free to contact me or have your staff contact Anna Schwamlein Howard, Policy Principal, Access and Quality of Care at Anna.Howard@cancer.org.

Sincerely,

Lisa A. Lacasse, MBA
President
American Cancer Society Cancer Action Network