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March 2, 2020

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-9916-P – Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2020
85 Fed. Reg. 7088 (February 6, 2020)

Dear Secretary Azar and Administrator Verma:

The American Cancer Society Cancer Action Network (ACS CAN) appreciates the opportunity to comment on the 2021 Notice of Benefit and Payment Parameters proposed rule. ACS CAN is making cancer a top priority for public officials and candidates at the federal, state, and local levels. 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. As the American Cancer Society's nonprofit, nonpartisan advocacy affiliate, ACS CAN is critical to the fight for a world without cancer.

Having comprehensive and affordable health insurance coverage is a key determinant in surviving cancer. Research from the American Cancer Society shows that uninsured Americans are less likely to get screened for cancer and thus are more likely to have their cancer diagnosed at an advanced stage when survival is less likely and the cost of care more expensive.[1] This not only impacts the 1.8 million Americans who will be diagnosed with cancer this year, but also the 16.9 million Americans living today who have a history of cancer.[2]

In general, we support many of the proposals contained in the 2021 Payment Notice, specifically the proposals related to special enrollment periods. Unfortunately, we are very concerned about the proposal to allow issuers to no longer count manufacturer coupons towards an individual's limitation on cost-sharing. This policy could hinder cancer patients' and survivors' access to medically appropriate therapies. We urge HHS to rescind the proposed policy.

We are also concerned that HHS' proposal related to auto-enrollment of individuals in zero premium plans is unduly burdensome and will create confusion for individuals. We urge HHS not to finalize the proposed policy.

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[1] E Ward et al, "Association of Insurance with Cancer Care Utilization and Outcomes," *CA: A Cancer Journal for Clinicians* 58:1 (Jan./Feb. 2008), http://www.cancer.org/cancer/news/report-links-health-insurance-status-with-cancer-care.

[2] American Cancer Society. *Cancer Facts & Figures 2020.* Atlanta: American Cancer Society; 2020.

III. PROVISIONS OF THE PROPOSED HHS NOTICE OF BENEFIT AND PAYMENT PARAMETERS FOR 2021

A. Part 146 – Requirements for the Group Health Insurance Market: Excepted Benefit HRAs Offered by Non-Federal Government Plan Sponsors

HHS proposes that non-federal governmental plan sponsors that offer an excepted benefit health reimbursement arrangement (HRA) would have to provide a notice to eligible participants that describes the various features of the excepted benefit HRA, including eligibility, annual or lifetime caps, and a description or summary of available benefits.

"Excepted benefit HRAs" are a new option for employers who want to provide employees funds to enroll in short-term, limited-duration (STLD) plans, supplemental plans (like cancer-only supplemental plans), or COBRA plans. In order to offer this excepted benefit HRA, the employer must also offer a group health plan – but the employee may choose not to enroll in this more comprehensive coverage. ACS CAN opposed this provision when HHS proposed it in 2018[3] because we are concerned that some employees would enroll *only* in an STLD or supplemental plan – forgoing more comprehensive coverage because of affordability issues or lack of understanding.

We appreciate that HHS' proposal to require notice regarding these excepted benefit HRAs attempts to provide employees with information regarding whether a plan provides comprehensive coverage. However, we note that HHS proposes this notice must be provided no later than 90 days *after* the employee becomes a participant in the excepted benefit HRA and annually thereafter. Being notified that the plan you enrolled in is not comprehensive insurance coverage *after* you have enrolled is not helpful to employees – particularly because employees will not have any way to change their enrollment. We urge HHS to strengthen this requirement by changing the timeframe to require employers to provide this notification during the enrollment period.

D. Part 155 – Exchange Establishment Standards and Other Related Standards under the Affordable Care Act

3. Automatic re-enrollment process

Since the inception of the Exchanges, CMS has maintained an automatic re-enrollment process for individuals who do not actively choose to remain in the same plan or to enroll in a different plan. While CMS intends to continue the auto-enrollment process generally, it proposes to make significant changes for individuals who are auto-enrolled with Advance Premium Tax Credits (APTCs) that would cover the enrollee's entire premium. Instead of being auto-enrolled with the APTCs, CMS proposes that these individuals be auto-enrolled without their APTC, thus requiring them to return to the Exchange, obtain an updated eligibility determination, and then actively enroll or re-enroll in coverage. CMS proposes this policy due to fear that auto re-enrollment may lead to incorrect expenditures of the advance premium tax credits (APTCs). CMS notes that if this proposal is finalized it intends to conduct consumer outreach and education.

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[3] ACS CAN Comments regarding REG–136724–17: Health Reimbursement Arrangements and Other Account-Based Group Health Plans; 83 Fed. Reg. 54420 (October 29, 2018). https://www.fightcancer.org/sites/default/files/ACS%20CAN%20Comments%20on%20HRA%20Rule%2012-28-18.pdf.

ACS CAN strongly opposes CMS' proposed policy and urges the Administration not to finalize this policy as proposed. We believe this policy will create an unnecessary hurdle for lower-income individuals to obtain access to the affordable health care to which they are entitled.

Auto-enrollment helps to ensure continuous coverage which is particularly important for lower income cancer patients and survivors. The preamble recognizes the benefits of autoenrollment, stating "[a]utomatic re-enrollment significantly reduces issuer administrative expenses, makes enrolling in health care more convenient for the consumer, and is consistent with general health insurance industry practice."[4] In the 2019 open enrollment period, 1.8 million individuals were auto-enrolled in coverage, including 270,000 people who had a zero premium plan.

As proposed, this policy is overly punitive. The proposed policy would apply to those whose income has changed during the year – and who may be eligible for less of a subsidy – and those who would still be eligible for a full subsidy.

We are particularly concerned because this policy could cause significant confusion to individuals who qualify for a zero-premium plan. Unless they proactively updated their information with the exchange, these individuals would be re-enrolled in a plan with no subsidy, meaning that they would get a bill for the full premium. These individuals have limited incomes, so a full premium would most likely be beyond their means. The proposal will result in significant consumer confusion and will likely result in individuals being unenrolled from coverage due to non-payment of premiums.

5. Special Enrollment Periods (SEP) (§ 155.420)

a. Newly Ineligible for Cost-Sharing Reduction Subsidies (CSRs)

HHS proposes to allow enrollees and dependents that become newly ineligible for CSRs to use a SEP to switch from a silver qualified health plans (QHPs) to a bronze or gold QHP.

ACS CAN supports the addition of this SEP. Because the non-payment of CSRs has necessitated the practice of silver-loading, premiums for silver-level plans are often significantly higher than bronze or gold plans. Enrolling in a silver plan is a logical choice for someone receiving CSRs, but if they lose this eligibility, it is equally logical for the individual to want to switch metal-level tiers. These individuals should not be locked into a plan choice they made based on being eligible for CSRs. This change may keep more individuals enrolled in quality insurance coverage by giving them access to more affordable premiums.

c. SEP Prospective Coverage Effective Dates

HHS proposes that the new effective date for SEPs through the federally-facilitated exchange (FFE) will be on the first of the month following plan selection. CMS cites the added benefits of minimizing gaps in coverage and ensuring that SEPs due to changes in subsidy eligibility are processed quickly.

ACS CAN strongly supports this provision, as it will prevent enrollees having gaps in coverage. Preventing gaps in coverage is very important, because at every education level, individuals with health insurance

[4] 85 Fed. Reg. at 7119.

are about twice as likely as those without it to have access to critical early detection cancer procedures.[5] 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.

E. Part 156 – Health Insurance Issuer Standards under the Affordable Care Act, Including Standards Related to Exchanges

3. State selection of EHB-benchmark plan for plan years beginning on or after January 1, 2020 (§ 156.111)

The Affordable Care Act permits states to require qualified health plans (QHPs) in the state to cover benefits beyond what is included in the state's Essential Health Benefits (EHB) benchmark, but states that choose to do so must defray the cost of these additional benefits either for the individual or the issuer on behalf of the enrollee. States would only have to defray the cost of benefits enacted after December 31, 2011. HHS proposes that states identify state-mandated benefits that are in addition to the EHB benchmark. If the state does not comply with this requirement, HHS will make the determination.

ACS CAN urges HHS to ensure that in adopting this policy, states provide an opportunity for public comment on state mandated benefits for which defrayal of the cost of the benefit may be required. On the final form provided to states, we urge HHS to include information regarding specific exceptions to the defrayal policy, for example provider mandates that require reimbursement for specific health care professionals or state anti-discrimination requirements related to service delivery.[6]

4. Essential Health Benefits Package (§156.130)

c. <u>Cost-sharing requirements (§ 156.130)</u>

In the 2020 Payment Notice, HHS finalized a policy stating 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 the enrollee's out-of-pocket costs would not be counted toward the enrollee's annual limitation on cost-sharing. This policy applied only in cases where manufacturer support was provided to a brand drug for which there was a generic equivalent. In the 2021 Payment Notice, HHS proposes to revise the 2020 policy in its entirety. HHS now proposes that, to the extent consistent with state law, plans and issuers have the flexibility to determine whether to include or exclude manufacturer coupon amounts from the annual limitation on cost sharing regardless of whether a generic equivalent is available. This proposed policy would apply to issuers of non-grandfathered individual and group market coverage, and all non-grandfathered group health plans

ACS CAN opposes this proposed policy and urges HHS to retain the policy finalized in the 2020 Payment Notice. ACS CAN supports the use of copay assistance programs because many individuals would otherwise not be able to afford the cost sharing associated with their physician-prescribed drugs – particularly new and innovate therapies. According to a recent Survivor Views survey, 17 percent of respondents reported using a manufacturer's coupon or assistance program to help them afford their

[5] 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.
[6] https://www.cms.gov/CCIIO/Resources/Data-Resources/ehb.

prescription medication.[7] 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 costs) unless (1) the prohibition is limited to instances when a true therapeutic alternative exists and is covered by the plan's formulary and (2) when medical allowances are made for individuals for whom the generic drug is contra-indicated.

We note that in the 2020 Payment Notice's proposed rule, HHS recognized this very reasoning when it said that "copayment support may help beneficiaries by encouraging adherence to existing medications regimes, particularly when copayments may be unaffordable to many patients."[8] We are concerned that the 2021 Payment Notice proposal does not address the practical reality that many patients rely on copayment support in order to be adherent to their required medications.

Complexity of cancer care requires access to multiple drug therapies: Cancer care often requires specialized treatments. Oncology drugs often have different indications, different mechanisms of action, and different side effects – all of which need to be managed to fit the medical needs of an individual. When enrollees are in active cancer treatment, it can be particularly challenging to manage co-morbid conditions. Oncologists take into consideration these and multiple other factors related to expected clinical benefits and risks of oncology therapies and the patient's clinical profile when making treatment decisions.

Cancer patients often take multiple medications to manage their disease and co-morbid conditions and it can be challenging to find an appropriate treatment regimen that works for the individual patient. In order to increase the likelihood of a successful outcome, patients need access to medically appropriate cancer treatments that are as targeted as possible. Delaying cancer care can result in negative health outcomes, as the cancer may grow or spread during the delay.

Proposed policy unfairly penalizes the patient: Under the new proposed policy, individuals could still use manufacturer coupons, but the cost would not count towards the enrollee's cost-sharing obligations, meaning that it will take longer for the individual to meet their deductible or hit their maximum out-of-pocket limit (MOOP). Most individuals will not be able to afford the entirety of their out-of-pocket costs and would be more likely to be non-adherent to their prescription drug regimen. Prescription drug noncompliance can lead to poorer health outcomes for the individual.

Lack of information to enrollees: While we appreciate the need for transparency, we are concerned that putting the onus on the issuer to inform the consumer about any policy to not count coupons towards MOOP is inadequate. HHS is not proposing any specific requirements regarding how the notice is to be displayed nor specific examples to help the enrollee or potential enrollee understand the impact of the proposed policy. Given that HHS is simply requiring that issuers provide notice, it is expected that different issuers will interpret this requirement differently, making it harder for navigators and assisters to direct enrollees or potential enrollees to one particular place in which to learn whether their issuer has chosen to adopt this policy. We also note that the proposed rule is silent on the extent to which

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[7] ACS CAN. Survivor Views: Surprise Billing and Prescription Cost and Coverage - Survey Findings Summary https://www.fightcancer.org/sites/default/files/National%20Documents/Survivor%20Views.Surprise%20Billing_Prescription%20Drugs%20Polling%20Memo%20FINAL.pdf.

[8] 84 Fed. Reg. at 290.

healthcare.gov and/or state-based marketplaces will be required to prominently display information on whether individual plans have chosen to adopt this policy.

Existing rules promote generic utilization: ACS CAN believes that generic drug utilization can, and should, be encouraged whenever medically appropriate. It appears HHS is trying to justify the proposal as a means to encourage the use of generic drugs. In the preamble, HHS notes "[w]e encourage issuers and group health plans to consider utilizing this proposed flexibility to find innovating methods to address the market distortion that occurs when consumers select a higher-cost brand name drug when an equally effective, medically appropriate generic drug is available."[9] If that is indeed HHS' intended purpose, then the existing policy (created by the 2020 Payment Notice) should stand because that policy would prevent copay coupons from counting towards an individual's cost-sharing limitations when a generic alternative exists. Many cancer therapies do not have a generic equivalent and the proposed policy unfairly penalizes patients regardless of the availability of a generic drug.

6. Promoting value-based insurance design

CMS describes a new "value-based model QHP" that it encourages insurers to consider. CMS is considering ways to allow consumers to identify a value-based QHP through HealthCare.gov (such as including "value-based" in the plan name or ways for HHS to designate a plan as "value-based").

ACS CAN supports CMS' goals of ensuring that patients receive high-value care, enabling consumers to identify high value care, and removing cost-sharing for evidence-based treatments that provide high value. One example on the list of high value services in Table 11 is tobacco cessation treatment. ACS CAN has long supported the removal of cost-sharing and other barriers for tobaccos cessation treatment to encourage more tobacco users to make quit attempts with evidence-based help.

However, ACS CAN urges plans and CMS to use caution regarding classifying services as "low value." In a VBID model, as CMS describes, low value services would have increased cost-sharing. This type of benefit design may make sense in therapeutic areas where patients and doctors have many choices. This is often not the case in the treatment of cancer. Especially when the patient has a rare cancer or co-morbidities, oncologists and cancer patients may only have one treatment choice. If that one choice is classified as low value, the patient will be unfairly penalized for something that is out of their control.

CMS states that "low value services are those services in which the majority of consumers would not derive a clinical benefit." Yet for those patients who do derive value – such as cancer patients – these services are of high value. For instance, many of the services in Table 11 labeled "commonly overused service categories with increased cost-sharing" are the categories of services that many cancer patients must use: outpatient specialist services, outpatient labs, high-cost imaging, x-rays and other diagnostic imaging, outpatient surgical services and non-preferred drugs.

Penalizing patients for the use of these services is unfair. For example, when a cancer patient with a rare cancer must see a doctor specializing in that cancer, the only specialist available in their area may be an outpatient specialist. This patient should not be penalized by higher cost-sharing.

[9] 85 Fed. Reg. at 7136.

Furthermore, we are concerned that even when VBID cost-sharing is appropriate for certain services, the incentives will not work because of a lack of transparency in pricing and cost-sharing. We recognize that HHS has currently proposed a rule that will require more transparency in patient costs, and if finalized, this rule may alleviate this particular concern in cases where a service is planned ahead of time and the patient requests an advanced estimate of costs. But many cancer patients still may not be able to understand or respond to the consequences of having one of these services until it is too late – and many may be reluctant to question their physician who has ordered the service. Consequently, the patient is penalized for following the recommendations of their physician – and the physician may be operating under a very different scheme of incentives. ACS CAN encourages plans to include careful and extensive provider outreach when implementing VBID policies in these categories, and we urge CMS to carefully monitor these activities. We also urge CMS to track and evaluate the number of appeals and disputes that VBID increased cost-sharing may generate.

CONCLUSION

Thank you for the opportunity to comment on the 2021 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