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Submitted Electronically at www.regulations.gov

March 02, 2020

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-9916-P
P.O. Box 8016
Baltimore, MD 21244-8016

Re: CMS-9916-P; Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2021; Notice Requirement for Non-Federal Governmental Plans

Dear Administrator Verma,

I am pleased to submit these comments on behalf of the Association of Clinical Oncology (the Association) in response to the Affordable Care Act Notice of Benefit and Payment Parameters in 2021 proposed rule, which was published in the Federal Register on February 6, 2020 (85 FR 7088).

The Association is a national organization representing nearly 45,000 physicians and other health care professionals specializing in cancer treatment, diagnosis, and prevention. We are also dedicated to conducting research that leads to improved patient outcomes, and we are committed to ensuring that evidence-based practices for the prevention, diagnosis, and treatment of cancer are available to all Americans.

The Association has significant concerns regarding two proposals in this rule; specifically, the inclusion of drug manufacturer coupons in the annual limitation on beneficiary cost sharing and automatic re-enrollment without advanced premium tax credits (APTCs). We believe these proposals have the potential to erode beneficiary access to affordable cancer care, as detailed below.

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We do not support the definition of cost-sharing to exclude drug manufacturer coupons. HHS should not create policy affording insurers the flexibility to determine if drug manufacturer coupons contribute to a beneficiary's cost sharing, as this has the potential to compromise patient access to affordable cancer care.

Our affiliate organization, the American Society of Clinical Oncology, has earlier expressed concerns regarding co-pay accumulator and co-pay maximizer programs.¹ These programs target specialty drugs for which manufacturers typically provide copay assistance. Such utilization management tactics negate the intended benefit of patient assistance programs—and remove a safety net for patients who need expensive specialty medications but cannot afford them. This can lead to poorer health outcomes and potentially higher costs to the health care system. We have growing concerns with co-pay accumulator programs such as the one outlined in this proposed rule, as it applies regardless if a generic equivalent is available or not.

Under this proposal, it is left to the discretion of the insurer whether manufacturer assistance will apply to a patient's copay or out-of-pocket maximum, creating transparency issues for patients. This lack of transparency in the implementation of copayment accumulator programs will likely lead to confusion among patients and create unnecessary barriers to access. The Association is concerned that beneficiaries will not have complete knowledge or full understanding of how the exclusion of drug manufacturer coupons from copays will impact their cost sharing. This proposal could jeopardize health outcomes, as patients may decide to forego or discontinue treatment or seek different treatment for non-medical reasons.

Additionally, with this proposal in place, it is likely that manufacturer assistance will not apply to a patient's copay or out-of-pocket maximum, therefore preventing patients from reaching their deductibles sooner. Copay accumulator programs generate large savings for employers and PBMs while increasing cost-sharing for patients. Co-pay accumulator programs and this proposal will shift healthcare costs away from plan sponsors and employers, and onto patients.

Many Association members describe the difficulty and time-consuming process involved in finding financial assistance for their patients. This additional complexity in coverage policy will only increase the administrative burden on practice staff, who will now need to understand the nuances of co-pay accumulators across different plans and then explain to patients why some of the assistance is not helping them to reach their deductible. The Association urges CMS not to alter the definition of cost sharing to exclude drug manufacturer coupons and believes that these coupons should be considered as part of beneficiary cost sharing, particularly for specialty drugs with associated with significant financial burden.

The Association does not support the proposal to automatically reenroll beneficiaries with \$0 coverage premiums without the advanced premium tax credits (APTCs) to which they are entitled.

The proposed rule makes changes that would alter the automatic reenrollment process for individuals purchasing coverage on the Marketplace. Under the rule, individuals currently receiving advance premium tax credits (APTCs) equal to or greater than their current premiums—and who therefore pay \$0 for coverage—would be automatically reenrolled in coverage. However, this

¹ American Society of Clinical Oncology Policy Brief: Co-pay Accumulators and Co-pay maximizers. September 2019. Available at <https://www.asco.org/sites/new-www.asco.org/files/content-files/advocacy-and-policy/documents/2019-AccumulatorsPolicyBrief.pdf>

reenrollment would not include some or all of their APTCs unless they recertified their financial need during open enrollment. This change could lead to beneficiaries who are eligible for \$0 premiums paying higher premiums if they are not aware of this proposed change.

CMS states that it would educate consumers affected by this change, and the agency has said that the proposal would encourage consumers to more actively consider their options and enroll in the right plan. However, the change could create confusion for beneficiaries who have previously been automatically reenrolled in their \$0 premium plan and could lead some individuals who qualify for \$0 plans to lose their coverage by failing to recertify their need for assistance.

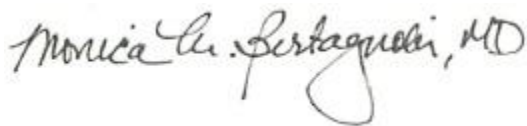
CMS describes an alternative proposal in which the APTCs for this population would result in premiums that are greater than \$0. We express concern that CMS has not articulated the basis on which to reduce the size of an individual's APTC as the Affordable Care Act prescribes the factors that must be used to calculate the value of an enrollee's APTC.

While the Association supports the agency's efforts to protect and offer reenrollment for beneficiaries who purchase coverage through the Marketplace, we do not support reenrollment of beneficiaries without APTCs. The purpose of reenrollment is to maintain seamless coverage. If a beneficiary misses the open enrollment window in which to reapply for tax credits and is unable to afford coverage without the APTCs, they would remain uncovered for the following year until the next enrollment period. The Association is very concerned that this proposed policy change would lead to gaps in coverage and urges CMS to reenroll beneficiaries with the APTCs intact.

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We appreciate the opportunity to comment on this Notice of Benefit and Payment Parameters for 2021. Please contact Gina Baxter (gina.baxter@asco.org) or Karen Hagerty (karen.hagerty@asco.org) with any questions or for further information.

Sincerely,

A handwritten signature in black ink that reads "Monica Bertagnolli, MD". The signature is written in a cursive style with a large, looped 'M' and 'B'.

Monica Bertagnolli, MD, FACS, FASCO
Chair, Association for Clinical Oncology