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March 4, 2016

Andrew Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Advance Notice of Methodological Changes for Calendar Year (CY) 2017 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2017 Call Letter

Dear Acting Administrator Slavitt:

The American Cancer Society Cancer Action Network (ACS CAN) appreciates the opportunity to comment on the Advance Notice of Methodological Changes for calendar year (CY) 2017 for Medicare Advantage (MA) capitation rates, Part C and D payment policies and the 2017 Call Letter. 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. As the nation's leading advocate for public policies that are helping to defeat cancer, ACS CAN ensures that cancer patients, survivors, and their families have a voice in public policy matters at all levels of government.

ACS CAN generally supports the policies contained in the Draft 2017 Call Letter and offers the following specific comments.

ATTACHMENT II: CHANGES IN THE PART C PAYMENT METHODOLOGY FOR CY 2017

Section E. Clinical Trials

CMS proposes to continue its policy of paying on a fee-for-service basis for qualified clinical trial items and services provided to Medicare Advantage (MA) beneficiaries that are covered under the relevant National Coverage Determinations on clinical trials.

ACS CAN opposes the current policy and urges CMS to require MA plans to cover the cost of clinical trials. Under the current policy – which CMS proposes to continue in CY 2017 – beneficiaries enrolled in MA plans are required to relinquish their MA coverage and revert to fee-for-service Medicare if they want to participate in a clinical trial. ACS CAN is concerned that this policy creates a strong disincentive for MA beneficiaries to enroll in clinical trials. For many serious or life-threatening diseases – like cancer – clinical trials may offer the best hope for successful treatment. Further, Medicare beneficiaries are notoriously underrepresented in clinical trials and, as a result, the effectiveness of a particular therapy in the Medicare population may not be known until after the product is introduced into the general marketplace. Thus, the Medicare program should consider incentivizing beneficiaries – not

creating disincentives – to participate in clinical trials. This is particularly important in light of the increased enrollment in MA plans.[1]

ATTACHMENT VI: CY2017 DRAFT CALL LETTER

Section II – Part C

Guidance on the Future of Provider Directory Requirements and Best Practices

CMS reiterated its focus on ensuring the accuracies of provider directories. The Draft Call Letter notes that some Medicare Advantage Organizations (MAOs) are testing new technologies designed to simplify the process of updating provider directories for physicians and other network participants. The Draft Call Letter also notes that among MA, Qualified Health Plans (QHPs) and the Medicaid managed care programs, MA provides the least prescriptive provider directory requirements.

ACS CAN is pleased that CMS recognizes the need for MA plans to provide accurate provider directories so that beneficiaries and their families can choose a plan that best meets the needs of the beneficiary. Cancer patients – including those who are newly diagnosed, in active treatment, and survivors – often choose a health plan based on the specialists included in the plan's network. We also appreciate the multi-stakeholder effort underway by AHIP to try and improve the provider directories.

We share CMS' concern that the MA program has the fewest data elements required for its provider directory. If regulatory action is needed, we urge CMS to promulgate regulations this year that would bring the MA provider directory requirements in line with those imposed on QHPs, including adding requirements that MA plans list whether the provider is accepting new patients.

Meaningful Difference (Substantially Duplicative Plan Offerings)

CMS regulations provide that MAOs offering more than one plan in a given service area must guarantee the plans are substantially different so that beneficiaries can easily identify the differences in order to determine which plan provides the highest value at the lowest cost to address their needs. The Draft Call Letter notes that CMS will use plan-specific per member per month out-of-pocket cost estimates to identify the meaningful differences among plans offered by the same MAO in the same service area.

ACS CAN supports CMS' proposal. While beneficiaries should have a choice of MA plan options, too many options can hinder a beneficiary's ability to make an informed choice. We agree with CMS that plan designs must be meaningfully different and that premiums alone will not satisfy the meaningful difference requirement.

Cost Sharing/Bundling and Facility

CMS expressed concern about the transparency of cost sharing for Medicare Advantage beneficiaries. The Draft Call Letter cites cases where an enrollee may receive a service in a facility that includes an additional facility fee that does not apply when the service is provided in a physician's office. While CMS would permit an MAO to impose higher cost-sharing based on the site of service, the Draft Call Letter

[1] *The 2015 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplemental Medical Insurance Trust Funds*, July 2015, available at https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/reportstrustfunds/downloads/tr2015.pdf.

makes clear that to the extent possible MAOs should include the enrollee's entire cost sharing responsibility in a single copayment.

ACS CAN supports CMS' position. Beneficiaries clearly should be made aware of their cost sharing responsibilities prior to receiving the service. We believe that MAOs should not be permitted to unbundle Medicare services and apply multiple cost sharing for one service. To the extent that there is a difference in cost sharing based on the site of service, these costs should be bundled and reflected as part of the cost sharing amount for the service bundle.

Section III – Part D

Improving Clinical Decision-Making for Certain Part D Coverage Determinations

The Draft Call Letter notes that Part D coverage determinations require a plan sponsor to notify the enrollee of its decision no more than 72 hours from receipt of the request for standard requests for benefits (24 hours for expedited requests). If the Part D plan is unable to obtain information needed to approve coverage before the expiration of these timeframes (despite its outreach efforts), it must issue a denial notice. CMS notes that when the 24- or 72-hour adjudication timeframe is impacted by a weekend or holiday (or both) the plan may be less likely to reach the prescriber before the expiration of the timeframe. Thus, CMS notes it is contemplating rulemaking that would allow extensions to Part D adjudication timeframes in certain limited circumstances such as: (1) the coverage determination level; (2) situations where the timeframe is impacted by a weekend or holiday; (3) requests for drugs that require prior authorization or step therapy pursuant to the plan's CMS-approved formulary; and (4) cases where the plan does not have all necessary information from the prescriber required to make a clinically appropriate decision based on approved criteria.

ACS CAN agrees with CMS' concern that access delays may occur when the Part D plan is unable to obtain the information necessary to make a coverage determination. However, we caution CMS to ensure that the proposed rulemaking would not simply extend the existing determination timeframes, thus delaying beneficiary access to medically necessary prescription drugs. Any proposed extensions must be narrowly tailored in scope to ensure they are not being misused by Part D plan sponsors. Prior to enacting rulemaking, CMS should consider piloting a very limited proposal to ensure that beneficiary access is not negatively impacted by its proposal to extend the timeframes as proposed.

Specialty Tiers

CMS proposes to increase the specialty tier threshold from $600 to $670. The Draft Call Letter notes this is the first threshold increase since CY 2008.

ACS CAN supports CMS' proposal to increase the specialty tier threshold. Prescription drugs in the specialty tier may have higher coinsurance. Beneficiaries incur more out-of-pocket spending for drugs in this tier compared to drugs in the lower tiers. Moreover, the exception process does not apply to drugs on the specialty tier. CMS should consider increasing the specialty threshold on an annual basis – rather than sporadically – to ensure that the program keeps pace with drug costs.

Conclusion

On behalf of the American Cancer Society Cancer Action Network we thank you for the opportunity to comment on the Draft 2017 Call Letter. 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 or 202-585-3261.

Sincerely,

Kirsten Sloan
Senior Policy Director
American Cancer Society Cancer Action Network