



American Cancer Society
Cancer Action Network
555 11th Street, NW
Suite 300
Washington, DC 20004
202.661.5700
www.acscan.org

March 5, 2018

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

Re: Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2019 draft Call Letter

Dear Administrator Verma:

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) 2019 for Medicare Advantage (MA) capitation rates, Part C and D payment policies and 2019 draft 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 2019 Call Letter and offers comments discussed below.

ATTACHMENT VI. DRAFT CY 2019 CALL LETTER

Section II – Part C

Colorectal Cancer Screening

We commend CMS' commitment to ensuring that Medicare beneficiaries have access to preventive services, including colorectal cancer screenings. Colorectal cancer is the third most common cancer in men and women.¹ In the Medicare population, colorectal cancer is the second leading cause of cancer related deaths.² Colorectal cancer accounted for nearly 11 percent of Medicare fee-for-service cancer payments in 2011.³ Fortunately incident rates have been declining in recent years, in large part due to the increase in colorectal cancer screening rates.

Most colorectal cancers result from abnormal growths (“adenomatous polyps”) in the lining of the colon that become cancerous over time.⁴ Most of these polyps can be identified and removed during a

¹ American Cancer Society. *Cancer Facts & Figures 2018*. Atlanta, GA: American Cancer Society; 2018.

² National cancer for Health Statistics, Prepared by the Surveillance and Health Services Research Program of the American Cancer Society, 2012.

³ Medicare five percent sample LDS SAF files, 2011. Analysis by Direct Research, LLC.

⁴ Winawer SJ. Natural history of colorectal cancer. *Am J Med* 1999;106:3S-6S; discussion 50S-1S.

colonoscopy; thus, in many cases, colorectal cancer is preventable through timely screening.⁵ Colonoscopy with the removal of polyps reduces mortality from colorectal cancer by 53 percent.⁶ Approximately 90 percent of those diagnosed with early stage cancer live five or more years. A colonoscopy can literally save a person's life when a polyp is found and removed.⁷ Of those people who will be newly diagnosed with colorectal cancer, nearly two-thirds are Medicare beneficiaries.⁸ Yet in 2015, about one in three people over age 65 were not up to date with their recommended colorectal cancer screenings.⁹ Preventing colorectal cancer through polyp removal or catching cancer at an earlier stage saves lives and can reduce costs for public payers and private insurance.

Unfortunately, under current Medicare policy, beneficiaries are still required to pay coinsurance when the preventive action of removing a polyp, abnormal growth, or suspicious-looking tissue occurs during a screening colonoscopy. Cost sharing for polyp removal during a screening colonoscopy may discourage patients from getting their screening altogether leading to higher costs for Medicare in the long-term. Yet the costs associated with advanced treatment and premature death due to colorectal cancer are largely avoidable with appropriate screening.

Medicare Advantage plans have greater flexibility with respect to coinsurance options for beneficiaries and several plans use this flexibility to waive cost-sharing for instances where a polyp is removed during a screening colonoscopy. We are very supportive of those plans that use this flexibility to waive coinsurance responsibility and would be supportive of any actions CMS may take to encourage additional plans to waive cost-sharing for routine colonoscopies.

Section III – Part D

Improving Drug Utilization Review Controls in Medicare Part D

Part D Opioid Overutilization Policy

ACS CAN supports policies that take a reasonable, balanced approach to addressing the opioid addiction epidemic and its associated risks, without harming patients who are using the medications appropriate to treat their pain. Many cancer patients and survivors legitimately need access to opioids to treat their pain. We view all proposals such as this one through the lens of the cancer patient and survivor.

The Criteria for and Timing of Access Restrictions

To continue to address high-risk overutilization of prescription opioids in the Part D program, CMS proposes to create a new requirement for plan sponsors to address plan members who are taking high doses of opioids. In its proposed call letter, CMS requires all plan sponsors to implement hard formulary-level cumulative opioid safety limits at point-of-sale at the pharmacy at a dosage level of 90 morphine

⁵ Zauber AG, Winawer SJ, O'Brien MJ, et al. Colonoscopic polypectomy and long-term prevention of colorectal-cancer deaths. *N Eng J Med* 2012;366:687-96.

⁶ Zauber et al. Colonoscopic Polypectomy and Long-Term Prevention of Colorectal-Cancer Deaths *N Engl J Med* 2012; 366:687-696.

⁷ Howlader N, Noone AM, Krapcho M, et al, eds. SEER cancer statistics review, 1975–2010, Bethesda, MD: National Cancer Institute. Available at http://seer.cancer.gov/csr/1975_2010/.

⁸ American College of Gastroenterology. Press Releases April 28, 2015. <http://gi.org/wp-content/uploads/2015/04/SCREEN-Act-ACG-Press-Release-FINAL-04282015.pdf>. [accessed June 3, 2016].

⁹ American Cancer Society, *Cancer Prevention and Early Detection Facts and Figures*. Atlanta, GA: American Cancer Society; 2017.

milligram equivalent (MME). This means that if a patient tries to fill one or multiple prescriptions for opioids that meets or exceeds an amount of 90 MME, the prescription order(s) will be flagged for review by the pharmacy to assess whether it is appropriate to fill. Until the flag is resolved by the pharmacy with the patient's doctor and the Part D plan sponsor, the patient will not be able to fill their full prescription. This restriction as proposed would apply to all patients with qualifying cumulative prescriptions – not just patients who appear to be doctor or pharmacy “shopping” in order to access more opioids and misuse them.

This proposal differs significantly from the November 2017 proposal for a retrospective Drug Utilization Review (DUR) in the recent Medicare Part C and D rules (which have not yet been finalized).¹⁰ First, the previous proposal had more robust criteria for flagging patients using opioids: patients would be flagged who are taking 90 MME or above and who have some combination of 4-6 opioid prescribers or pharmacies. This current proposal only includes the first part of these criteria. As we stated in our comments on the previous proposal:

A prescription for a high dose of opioids should not be considered an automatic risk factor for misuse and abuse without significant high-quality evidence showing that it is an independent risk factor regardless of individual patient characteristics or other risk criteria. Patients being treated for cancer, requiring palliative care, or those at the end of life often do require high doses of these drugs. Including a high dose of drugs as the only criteria in clinical guidelines [or qualifying criteria for a concurrent DUR] would likely result in an unmanageably large program size, as well as unduly impact patient access.¹¹

Secondly, the previous rule proposed a retrospective process: CMS or a plan sponsor would flag a patient in its system based on past claims, then conduct case management. Only after the conclusion of that case management (or failure of the doctor to respond to case management attempts) would the patient become aware of any access restrictions. Furthermore, if the patient's doctors have cooperated with case management, the patient would be made aware of the access restrictions in advance of trying to fill a prescription, and presumably would be able to plan for such changes before running out of medication or the situation becoming more urgent.

In short, the patient access restriction under the November 2017 proposed rule would come at the end of the process. In this new proposal, the patient access restriction would be the first element in the chain of events. Unless the patient's doctor has provided the patient with prior warning about the requirement, the patient would arrive at the pharmacy expecting to fill her prescription – possibly in urgent pain, possibly with no more supply of medication – and be prevented from filling the full prescription. This failure to fill the prescription at the pharmacy then triggers a process in which the edit is overruled (thus enabling the patient to obtain the drug) or the prescription is changed by the patient's physician.

¹⁰ CMS-4182-P – Medicare Program; 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 Proposed Rule. 82 Fed. Reg. 56336 (November 18, 2017).

¹¹ See ACS CAN Comments on Medicare Part C and D Proposed Rule. January 17, 2018.

<https://www.acscan.org/policy-resources/acs-can-comments-medicare-part-c-and-d-proposed-rule-1>.

In sum, ACS CAN has serious concerns about a policy that restricts a patient's access to their prescribed medications as the first step. We therefore recommend that CMS reconsider the proposed process so that the prescriber, pharmacy and plan sponsor are required as the first step to address whether the prescription is medically appropriate before patients fill their prescription. We believe the process outlined for the retrospective DUR in the previous rule strikes a more appropriate balance between addressing potential misuse and abuse and protecting patient access.

Exceptions to Access Restrictions

CMS states that "sponsors should continue to apply specifications to account for known exceptions, such as hospice care; cancer diagnoses...and high-dose opioid usage previously determined to be medically necessary such as through coverage determinations, prior authorization, case management or appeals processes."

It is unclear when these exceptions are applied regarding the concurrent DUR. Are the exceptions applied before the hard edit is placed in the system, so that a cancer patient taking dosages ≥ 90 MME would not encounter the edit at all, and be able to fill their full prescription without trouble? Or is the exception applied while the plan sponsor resolves the edit with the pharmacy and prescriber, resulting in the cancer patient not being able to leave the pharmacy with her full prescription? Do all plan sponsors apply the exceptions at the same point in the process, or is there variation? It is also unclear how plan sponsors are required to define the cancer exception, and whether that definition is uniform across all sponsors. If CMS finalizes this proposal, we urge CMS at the very least, to clarify answers to these questions.

Patient Protections

The proposal does include several provisions aimed at minimizing disruption to patient treatment, including:

- Allowing beneficiaries to receive a 7-day supply of the prescription that triggered the hard edit while the edit is resolved;
- Emphasizing to plan sponsors that requests for exceptions to override the hard edit should be given expedited review;
- Expecting plan sponsors to "only rely on prescriber attestation that the higher MME is medically necessary to approve dosing" when the dosage amount is the only issue in dispute;
- Instructing plan sponsors to make exceptions for "high-dose opioid usage previously determined to be medically necessary such as through coverage determinations, prior authorization, case management or appeals processes," so that a patient should conceivably only have to encounter a hard edit once;¹²
- Emphasizing the importance of sponsors being able to efficiently process exceptions and appeals, including these expedited requests; and
- Stating that CMS will monitor the implementation of these hard edits, including complaints data, with a timeline for data collection and analysis.

¹² It is unclear whether this exception would be carried over if the patient changes Part D plans. ACS CAN encourages CMS to clarify and explore ways to implement this in plan sponsor transitions.

If, despite our concerns, CMS elects to move forward with the concurrent DUR program restricting patient access as discussed in previous sections, it is crucial that these measures also remain in the final rule because they will at least potentially minimize the impact of the restrictions on cancer patients and survivors who need access to these treatments. We strongly urge CMS to monitor this policy carefully and encourage the agency to be diligent and transparent in doing so.

Conclusion

On behalf of the American Cancer Society Cancer Action Network we thank you for the opportunity to comment on the draft 2019 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,

A handwritten signature in black ink, appearing to read "Lisa Lacasse", written over a light gray horizontal line.

Lisa Lacasse

Deputy President & Senior Vice President, Strategy & Operations
American Cancer Society Cancer Action Network