

**ASSOCIATION CHAIR
OF THE BOARD**

Monica M. Bertagnolli, MD,
FACS, FASCO

ASSOCIATION TREASURER

Eric J. Small, MD, FASCO

ASSOCIATION DIRECTORS

Howard A. "Skip" Burris, III, MD,
FACP, FASCO

Laurie E. Gaspar, MD, MBA,
FASTRO, FACR, FASCO

Carolyn B. Hendricks, MD,
FASCO

Reshma Jagsi, MD, DPhil,
FASTRO, FASCO

Michael P. Kosty, MD, FACP,
FASCO

Kurt R. Oettel, MD

Lori J. Pierce, MD, FASTRO,
FASCO

Everett E. Vokes, MD, FASCO

NON-VOTING DIRECTOR

CHIEF EXECUTIVE OFFICER

Clifford A. Hudis, MD,
FACP, FASCO

July 20, 2020

Seema Verma

Administrator

Centers for Medicare & Medicaid Services

Department of Health and Human Services

Attention: CMS-1735-P

P.O. Box 8013

Baltimore, MD 21244

Submitted Electronically at www.regulations.gov

Re: Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements [CMS-2482-P]

Dear Administrator Verma,

I am pleased to submit these comments on behalf of the Association for Clinical Oncology (ASCO) in response to the *Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements* proposed rule published in the Federal Register on June 19, 2020.

ASCO 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, including Medicaid beneficiaries.

* * * * *

ASCO thanks CMS for its exemption of Medicaid beneficiaries undergoing cancer treatment from its proposed additional opioid drug utilization review (DUR) requirements and encourages the agency to maintain flexibility in program edits and review for special populations.

Since 1993, each state has been required to develop a drug utilization review (DUR) program targeted, in part, at reducing abuse and misuse of outpatient prescription drugs covered under the State's Medicaid Program. Each state DUR program consists of

prospective drug use review, retrospective drug use review, data assessment of drug use against predetermined standards, and ongoing educational outreach activities.

The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act, October 24, 2018 (the SUPPORT for Patients and Communities Act) includes additional measures to combat the opioid crisis. These provisions establish drug review and utilization standards to supplement existing requirements, in an effort to reduce opioid-related fraud, misuse and abuse. State implementation of these strategies was required by October 1, 2019.

In order to ensure a minimum baseline standard across states, CMS intends to codify in regulation proposed baseline safety edits, claims review automated processes, and fraud and abuse process requirements as described in the proposed rule. Accordingly, the provisions of the proposed rule would implement opioid-related requirements established in the SUPPORT for Patients and Communities Act and further implement requirements under section 1927(g) of the Social Security Act, in an effort to reduce prescription-related fraud, misuse and abuse.

Specifically, CMS is proposing in the rule the following: limits on days' supply for opioid naïve beneficiaries; opioid quantity limits with dose optimization (dose optimization is a method to consolidate the quantity of medication dispensed to the smallest amount required to achieve the desired daily dose and regimen); early fill limitations; and maximum daily morphine milligram equivalent (MME) limits.

CMS is also proposing that states must have in place a claims automated review process (as designed and implemented by the state) that indicates when an individual enrolled under the state plan (or under a waiver of the state plan) is prescribed opioids in excess of above-proposed limitations identified by the state. States should continuously monitor opioid prescriptions, including overrides of safety edits by the prescriber or dispenser on initial fill days' supply for opioid naïve patients, quantity limits, therapeutically duplicative fills, early refills and maximum daily MME limitations on opioid prescriptions.

CMS is also implementing a provision of the SUPPORT Act that requires covered providers who are permitted to prescribe controlled substances and who participate in Medicaid to query qualified Prescription Drug Monitoring Programs (PDMPs) before prescribing controlled substances to most Medicaid beneficiaries, beginning October 1, 2021.

The above described drug utilization review requirements will not apply for individuals who are receiving hospice or palliative care or those in treatment for cancer; residents of a long-term care facility, a facility described in section 1905(d) of the Social Security Act (that is, an intermediate care facility for the intellectually disabled), or of another facility for which frequently abused drugs are dispensed for residents through a contact with a single pharmacy; or other individuals the state elects to treat as exempted from such requirements. **ASCO appreciates the exemption for patients in treatment for cancer and urges CMS to also consider the special circumstances of cancer survivors.**

In a February 2019 letter sent jointly to ASCO, the American Society of Hematology (ASH) and the National Comprehensive Cancer Network (NCCN), the Centers for Disease Control and Prevention (CDC) acknowledged that national, evidence-based guidelines from these organizations provide useful guidance for special populations such as cancer survivors, stating that the relationship of benefits to risks of opioid use is unique in this population. ASCO urges CMS to consider this clarification from the CDC and consider also exempting cancer survivors from the proposed provisions in this rule.

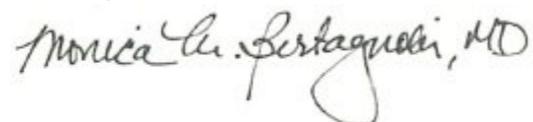
ASCO thanks CMS for recognizing the special needs of patients with cancer, especially in this time of uncertainty and when many immune-compromised patients with cancer are sheltering at home and may not be able to make frequent trips to visit their physician or a pharmacy. It is vital that such patients receive relief from requirements such as early-fill rules and dose optimization, as patients with cancer may at any time experience worsening disease and concomitant pain, necessitating dosage changes, additional dose units for breakthrough pain, or earlier-than-anticipated refills. It is also important that patients with cancer be spared as many unnecessary trips as possible, and early refills of steady-dose prescriptions can allow for that where possible.

Finally, CMS is requiring that Medicaid providers prescribing controlled substances check a qualified PDMP, beginning October 2021. Most of our members already routinely check qualified PDMPs prior to issuing prescriptions for controlled substances. We again urge CMS—as we have in earlier comments—to work with states to ensure that mechanisms to decrease administrative burden are implemented, such as allowing queries by designated staff and “batch checking” prior to patient visits. We also urge states and health information technology vendors to work with stakeholders to enable full integration of PDMP query into existing electronic health record systems.

* * * * *

We thank CMS for the opportunity to provide comments on this proposed rule. If you have any questions or need additional information, please contact Gina Baxter (gina.baxter@asco.org) or Karen Hagerty (karen.hagerty@asco.org).

Sincerely,

A handwritten signature in cursive script that reads "Monica L. Bertagnolli, MD". The signature is written in dark ink and is positioned above the typed name and title.

Monica Bertagnolli, MD, FACS, FASCO
Chair of the Board
Association for Clinical Oncology