March 13, 2023

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244
Attention: CMS–0057–P; RIN 0938-AU87

Submitted Electronically via www.regulations.gov

Re: Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally- Facilitated Exchanges, Merit-Based Incentive Payment System (MIPS) Eligible Clinicians, and Eligible Hospitals and Critical Access Hospitals in the Medicare Promoting Interoperability Program. [CMS–0057–P; RIN 0938-AU87]

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Dear Administrator Brooks-LaSure,

We are pleased to submit this comment letter on behalf of OneOncology in response to the formal request for comments regarding the proposed rule "Advancing Interoperability and Improving Prior Authorization Processes" (CMS–4201–P, RIN 0938–AU96).

OneOncology was founded by community oncologists, for community oncologists, with the mission of improving the lives of everyone living with cancer. Our goal is to enable community oncology practices to remain independent and to improve patient access to care in their communities, all at a lower cost than in the hospital setting. OneOncology supports our platform of community oncology practices through group purchasing, operational optimization, practice growth, and clinical innovation. Our 750 cancer care providers care for 478,000 patients at 546 sites of care nationwide, including approximately 238,000 Medicare enrollees (inclusive of Medicare Advantage), 129,000 traditional Medicare beneficiaries, and 60,000 Medicaid enrollees during 2022.

OneOncology acknowledges the importance CMS's ongoing efforts to improve payment policies for cancer care services that better achieve the Quadruple AIM: (1) Access to high quality cancer care for Medicare beneficiaries; (2) Enhancing the patient experience; (3) Minimizing the cost of cancer care for patients and the Medicare Trust Funds; (4) Workforce health among care teams dedicated to the treatment of cancer and blood disorders and whom OneOncology serves.

OneOncology supports the efforts of CMS to reform utilization management prior authorization policies aimed at removing unnecessary barriers and delays to high quality care for Medicare Advantage (MA) and Medicaid (MCD) enrollees being treated for cancer and blood disorders.

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Executive Summary of OneOncology's Comments on the Prior Authorization Proposed Rule:

1. **We urge CMS apply the prior authorization-related provisions of this proposed rule to the prior authorization of drugs.**

   As currently proposed, by excluding drugs from the prior authorization-related provisions of this proposed rule, Medicare beneficiaries being treated for cancers and blood disorders will continue to suffer unnecessary delays in receiving the care they need to enhance and maintain their health. In addition, providers who treat patients with these conditions would continue to contend with inefficiencies in care delivery stemming from the current state of overly burdensome prior authorizations processes of Medicare Advantage Organization (MAOs), Medicaid (MCD) plans, and Medicare Part D Plans (MPDPs).

2. **We support CMS's efforts to encourage the implementation of gold-carding programs among MAOs, MCD plans, and MPDPs.**

   To maximize the benefits to patient care that could potentially stem from well-implemented gold-carding programs, CMS should issue clearer requirements that payers advance gold-carding programs, and apply such requirements to MAOs, MPDPs, Medicaid payers, commercial exchanges, fully-funded commercial health plans, and self-funded commercial health plans**.**

3. **We urge CMS to rescind the MIPS Promoting Interoperability (PI) Performance Category reporting requirements related to use of PARDD APIs.**

   Given the universal support among providers for increasing efficiency in prior authorization processes, the implementation (by payers and EHR technology companies) of well-designed, efficient Prior Authorization Documentation and Decision (PARDD) API technology would be quickly and widely embraced by healthcare providers. The Promoting Interoperability (PI) requirements of MIPS are already too inefficient and burdensome, and prioritize documentation and paperwork over the importance of provider-patient communication and patient-centered care. By requiring providers to report the proposed PARDD API utilization measure under the MIPS PI performance category, healthcare providers and patient care teams could be further burdened by suboptimized technologies and documentation requirements that detract from well-coordinate high-quality patient care.

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1. **In finalizing this proposed rule, or through future rule-making, CMS should apply the prior authorization-related provisions of this proposed rule to Medicare Advantage Organizations (MAOs), Medicaid (MCD) plans, and Medicare Part D Plans (MPDPs) for medical and pharmacy benefit drugs that require prior authorization.**

Background:

We fully support CMS's policy intentions described throughout this proposed rule relating to improving prior authorization processes for the purposes of minimizing the detrimental impact to Medicare Advantage (MA) and Medicaid (MCD) enrollees and minimizing unnecessary burdens in the time and cost that healthcare providers must expend to navigate the burdensome inefficiencies of current state prior authorization processes.

Throughout this proposed rule CMS describes reforming the prior authorization processes for drugs as a key consideration in promoting access to high-quality, well-coordinated care for MA and MCD enrollees, in stating for example:

- *87 FR 76243:*

  "…In the CMS Interoperability and Patient Access final rule (85 FR 25523), we gave examples of how claims data can be used to benefit patients and providers. For example, inconsistent benefit utilization patterns in an individual's claims data, such as a failure to fill a prescription or received recommended therapies, can indicate to a provider or payer that the individual has had difficulty financing a treatment regimen and may require less expensive prescription drugs or therapies, additional explanation about the severity of their condition, or other types of assistance.

  Patients tend to receive care from multiple providers, leading to fragmented patient health records where various pieces of an individual's longitudinal record are locked in disparate, siloed data systems. With patient data scattered across these disconnected systems, it can be challenging for providers to get a clear picture of the patient's care history, and patients may forget or be unable to provide critical information to their provider. This lack of comprehensive patient data can impede care coordination efforts and access to appropriate care."

- *87 FR 76286:*
  "….Additionally, physicians reported that most prior authorizations are still done through phone calls and faxes, with only 26 percent reporting that they have an EHR system that supports electronic prior authorization for prescription medications.[70]"

Furthermore, referenced documents cited throughout this proposed rule that support the prior authorization reforms within this proposed rule clearly acknowledge the importance of applying these reforms to medical and pharmacy benefit drugs. This is notably the case the reforms proposed within Section II.D., on "Improving the Prior Authorization Process."

For example, throughout the published ONC *Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs,* prior authorization for drugs and

medications are emphasized as a key pillar of necessary policy reforms,[1] as described under "Strategy 3: Leverage health IT to standardize data and processes around ordering services and related prior authorization processes; Recommendation 1: Evaluate and address other process and clinical workflow factors contributing to burden associated with prior authorization":

> *"…These efforts should also consider how the use of prior authorization within the EHR workflow is required for medications and medical services and items, as well as the clinical and coverage guidelines used by payers during the review of a prior authorization request, and how improved integration can help to reduce provider burden."* [emphasis added]

Therefore, CMS's explicit exclusion of drugs from the prior authorization-related reforms of this proposed rule is contradictory to the acknowledged importance of applying such reforms to prior authorization for drugs. Throughout this proposed rule CMS has not put forth clear reasoning for the exclusion of drugs from these prior authorization reforms, and to the contrary, CMS emphasizes that well-coordinate patient care could be enhanced by applying these reforms to the prior authorization of drugs.

Below we've noted some specific examples of the provisions of this proposed rule that should be rendered applicable to drugs in finalizing this proposed rule or through future CMS rulemaking:

- Section II.A.2.a.: Provisions of the Proposed Rule; Patient Access API; Enhancing the Patient Access API; Prior Authorization Information [87 FR 76245].
- Section II.B.2.a.: Provisions of the Proposed Rule; Provider Access API; Proposed Requirements for Payers: Provider Access API for Individual Patient Information [87 FR 76258].
- Section II.C.3.: Provisions of the Proposed Rule; Payer to Payer API; Payer to Payer API Technical Standards [87 FR 76270].
- Section II.D.3.a.: Provisions of the Proposed Rule; Improving the Prior Authorization Process; Prior Authorization Requirements, Documentation, and Decision (PARDD) API [87 FR 76291].

Absent any further clarification from CMS that would apply these provisions listed above (among other provisions throughout this proposed rule) to the prior authorization of drugs (especially those described within Section II.D. "Improving the Prior Authorization Process"), it's unlikely that the benefits of well-coordinated high-quality patient care stemming from such provisions would apply to MA and MCD enrollees being treated for cancers and blood disorders. These concerns are consistent with survey findings by both the American Medical Association (AMA) and America's Health Insurance Plans (AHIP) that describe current technology-related limitations in streamlining the prior authorization process. [2,3]

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[1] Office of the National Coordinator for Health Information Technology. *Strategy on Reducing Burden Relating to the Use of Health IT and EHRs.* Feb. 2020. Pg. 46. Accessed via https://www.healthit.gov/sites/default/files/page/2020-02/BurdenReport_0.pdf.

[2] American Medical Association (2021) Update: Measuring Progress in Improving Prior Authorization. Accessed via https://www.ama-assn.org/system/files/prior-authorization-reform-progress-update.pdf.

[3] AHIP 2022 Survey on Prior Authorization Practices and Gold Carding Experiences. Accessed via https://www.ahip.org/documents/2022-Prior-Auth-Survey-Results-FINAL.pdf.

2. CMS should further encourage "Gold-carding Programs for Prior Authorization" and clarify that such programs should apply to prior authorization for drugs.

Background:

CMS defines "gold-carding" programs as efforts to "relax or reduce prior authorization requirement for providers that have demonstrated a consistent pattern of compliance," and further notes that, "in such programs, providers are relieved of requirements to submit prior authorization requests based on data indicating their adherence to submission requirements, appropriate utilization of items or services, or other evidence-driven criteria."[87 FR 76307]

We agree with the comments that have been made to CMS by various stakeholders in the past that suggest "the prior authorization process could be significantly more efficient and cost effective for all parties if these program were more broadly implemented."

Therefore we support CMS efforts to encourage MAOs, MCD plans, and MPDPs to expand the use of gold-carding programs. Specifically we support the suggestion within this proposed rule that broad applicability of gold-carding should be incorporated in quality star ratings for MAOs and QHPs.

For reasons we have emphasized elsewhere throughout these comments, CMS should pursue more detailed rule-making regarding how MAOs and MCD plans implement gold-carding, and should require that gold-carding programs apply to drugs. Absent such mandates, it's unlikely that payers will leverage gold-carding programs to the benefit of Medicare enrollees undergoing treatment for cancers and blood disorders. Despite the current state of clear evidence-based standards for use of prescription medications to treat these conditions, a recent survey of commercial health plans noted that only 21% reported "more frequent use of gold-carding" for prescription medications (compared to 58% for other medical services).[4]

Applying gold-carding programs to drugs will be necessary to ensure that the potential advantages of these programs are realized by Medicare enrollees undergoing treatment of cancers and blood disorders, i.e. by reducing unnecessary delays in treatments. Applying gold-carding programs to drugs will also improve the efficiency of high-quality care delivery for oncologists and hematologists and their care teams.

3. CMS should indefinitely rescind the provisions of this proposed rule requiring that healthcare providers submit the proposed electronic prior authorization measure as a requirement of the Merit-Based Incentive Payment System (MIPS) Promoting Interoperability (PI) Performance Category.

[4] AHIP 2022 Survey on Prior Authorization Practices and Gold Carding Experiences. Accessed via https://www.ahip.org/documents/2022-Prior-Auth-Survey-Results-FINAL.pdf.

Background:

Given the widespread support among providers for making the prior authorization process more efficient, the implementation by payers and EHR companies of well-designed and efficient PAARD API technology would likely be embraced by healthcare providers and healthcare provider organizations without any additional regulatory burden from expanding the MIPS Promoting Interoperability (PI) performance category requirements to include the proposed prior authorization measure. However, by mandating use of PARDD API technologies within the PI requirements of MIPS, healthcare providers and patient care teams could be further burdened by suboptimized PARRD API technologies and documentation that detract from patient care. The Promoting Interoperability requirements of MIPS are already too inefficient and burdensome, and prioritize documentation and paperwork over the importance of provider-patient communication and overall patient care.

The ONC's *Strategy on Reducing Burden Relating to the Use of Health IT and EHRs* published in Feb. 2020 includes the following strategies ONC could leverage to reduce provider burden caused by expansion of MIPS reporting requirements and suboptimized EHR technology[5]:

1) *Leverage health IT to standardize data and processes around ordering services or equipment and related prior authorization processes.*
2) *Improve usability through better alignment of EHRs with clinical workflow; improve decision making and documentation.*
3) *Promote user interface optimization in health IT that will improve the efficiency, experience, and end user satisfaction.*
4) *Promote harmonization surrounding clinical content contained in health IT to reduce burden.*
5) *Improve health IT usability by promoting the importance of implementation decisions for clinician efficiency, satisfaction, and lowered burden.*
6) *Address program reporting and participation burdens by simplifying program requirements and incentivizing new approaches that are both easier and provide better value to clinicians.*
7) *Leverage health IT functionality to reduce administrative and financial burdens associated with quality and EHR reporting programs.*
8) *Improve the value and usability of electronic clinical quality measures while decreasing health care provider burden.*

Many of the provisions of this proposed rule could lead to meaningful progress towards strategy #1 listed above, most notably the provisions found in Section II.B ("Proposed Requirements for Payers: Provider Access API for Individual Patient Information") and Section II.D ("Improving the Prior Authorization Process"). However, expanding the MIPS PI performance category measures to include the proposed prior authorization measure could be counterproductive relative to all the other strategies listed above. Therefore, prior to finalizing the requirement that providers report the proposed prior authorization measure under the MIPS PI category, CMS should request stakeholder comments from providers validating that use of PARDD API technologies and other

[5] Office of the National Coordinator for Health Information Technology. *Strategy on Reducing Burden Relating to the Use of Health IT and EHRs.* Feb. 2020. Pg. 49-54. Accessed via https://www.healthit.gov/sites/default/files/page/2020-02/BurdenReport_0.pdf.

prior authorization reforms within this proposed rule could be augmented through requiring the proposed prior authorization measure, instead of creating unnecessary provider burden.

Furthermore, the measure specifications for the propose prior authorization PI performance category reporting could become particularly burdensome based on parameters that CMS has requested public comments to address, for example:

- *What challenges will providers face in identifying those payers that have the PARDD API technology in order to accurately include eligible prior authorization requests in the denominator? [87 FR 76314]*
  - At this time, it remains completely unclear as how providers could accurately determine which payers have implemented PARDD API technology and how a provider will be able to determine the number of prior authorization requests that should be counted in the denominator of this measure.

- *What challenges will providers face in performing the actions included in the measure specifications and successfully reporting the measure if certification criteria are not available in the ONC Health IT Certification Program at the time providers are required to report the measure under the Medicare Promoting Interoperability Program or MIPS Promoting Interoperability performance category? [87 FR 76314]*
  - If certification criteria are not available in the ONC Health IT Certification Program at the time providers are required to report the measure under the PI performance category of MIPS, providers will be at risk of incurring financial penalties for this measure despite a lack of efficient technology solutions to perform the described actions and report the numerator and denominator of the measure.

- *With the understanding that ONC may consider policies in the ONC Health IT Certification Program that could further support this measure, are there alternate implementation timeframes that should be considered? [87 FR 76314]*
  - We urge CMS to suspend the requirement to report the proposed prior authorization MIPS PI measure until the requirements of this proposed rule that require payers' implementation of PARDD APIs have been in effect for at least three years. This timeline would allow CMS to consider whether expansion of MIPS PI requirements to include a prior authorization measure is actually necessary to augment provider use of efficient, well-implemented PARDD APIs. This timeline would also allow CMS to request comments from providers with experience using PARDD APIs to verify that such technology solutions are actually enhancing efficiency and reducing provider burden, instead of detracting from patient care by being unduly burdensome.

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We appreciate this opportunity to submit comments on this prior authorization proposed rule as these proposed policies relate to our common goals of achieving the Quadruple Aim in cancer care.

You may contact me or David Eagle, MD (deagle@nycancer.com), Chair of the OneOncology Advocacy Committee, at any time with any questions regarding these comments.

Sincerely,

Jeff Patton, MD
Chief Executive Officer
OneOncology