March 13, 2023

Xavier Becerra
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Re: CMS-0057-P–Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Advancing Interoperability and Improving Prior Authorization Process for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, and Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges
87 Fed. Reg. 76238 (December 13, 2022)

Dear Secretary Becerra:

The American Cancer Society Cancer Action Network (ACS CAN) appreciates the opportunity to comment on the proposed rule related to interoperability and improvements with the prior authorization process. ACS CAN is making cancer a top priority for public officials and candidates at the federal, state, and local levels. ACS CAN empowers advocates across the country to make their voices heard and influence evidence-based public policy change, as well as legislative and regulatory solutions that will reduce the cancer burden. As the American Cancer Society's nonprofit, nonpartisan advocacy affiliate, ACS CAN is more determined than ever to end cancer as we know it, for everyone.

ACS CAN offers comments on the Patient Access Application Programing Interface (API) and the requirements to improve the prior authorization process. We support many of the proposals to improve the prior authorization process, but urge HHS to include prescription drugs both in the Patient Access API and the improvements to the prior authorization processes because prescription drugs are often a critical component of cancer care.

II. Provisions of the Proposed Rule

A. Patient Access Application Programing Interface (API)

Certain payers (including Medicare Advantage Organizations, state Medicaid fee-for-service programs, CHIP fee-for-service programs, Medicaid managed care plans, CHIP managed care entities, and Qualified Health Plan (QHP) issuers on the federally-facilitated exchanges (FFEs)) are required to implement and maintain Application Programming Interfaces (API) that allow patients to use health apps in order to access certain data. Under the proposed rule, HHS would require these payers to include information about patients' prior authorization decisions and would require payers to report annual metrics to CMS about patient use of the Patient Access API.

Inclusion of prescription drugs: ACS CAN supports HHS' proposal to include prior authorization information of health care services (except prescription drugs) as part of the Patient Access API. However, we are disappointed that HHS does not propose to require information regarding prior authorization of prescription drugs to be included in the Patient Access API and urge HHS to require that payers include information related to prescription drugs as well (discussed in more detail below).

Inclusion of caregivers: We also note that individuals with complex conditions like cancer often rely on caregivers to assist them with various activities including managing appointments, medication adherence, and insurance issues. We urge HHS to clarify how an individual can include caregivers as part of their Patient Access API.

Reporting requirements: ACS CAN is pleased that HHS is proposing to require payers to report aggregated and de-identified metrics to CMS on an annual basis regarding how patients use the Patient Access API. We believe it is important to monitor the extent to which individuals are accessing their Patient Access API. At the same time, we note that some individuals may wish to access the information contained in the Patient Access API (for example, information regarding the status of their prior authorization claim) but may not have access to the appropriate software and/or app. We urge HHS to ensure that entities are required to provide an enrollee with the ability to access information through written communication if they so choose. Many individuals may prefer to access certain information in written form (either because they feel uncomfortable with electronic communications, they may not have regular access to a mobile device and/or high-speed internet). These individuals should not be disadvantaged because they are unable to access a Patient Access API.

D. Improving Prior Authorization Processes

HHS seeks to improve the prior authorization process for payers, providers, and patients. ACS CAN has been concerned about the increase in use of prior authorization[1] and its impact on cancer patients. Given the complexity of cancer care, treatments and services are often subject to prior authorization requirements. However, if not conducted appropriately prior authorization can hinder access to medically necessary care. For example, in a recent survey of cancer patients, 79 percent report that prior authorization is required by their insurer for treatment and services such as imaging (59%), surgical procedures (37%), prescription drugs (31%) and radiation therapy (28%).[2]

We offer the following thoughts on HHS' proposal:

Prescription Drugs: HHS suggests that because the processes and standards for prior authorization applicable to drugs differ from other items and services, the rule would not apply to any drugs including outpatient drugs, physician-administered drugs, or those that may be administered in a pharmacy or hospital. HHS' stated rationale for excluding drugs is that there are existing laws and regulations that may apply to prior authorization for drugs.

ACS CAN urges HHS to reconsider excluding drugs from this rule. Including prescription drugs in the rule will benefit patients who often encounter unnecessarily long delays in obtaining their medically necessary prescription drugs while their prior authorization request is being adjudicated. It will also further HHS' stated goal of this proposed rule is "to modernize the health care system" by among other things "establish[ing] policies to make the prior authorization process more efficient and transparent."[3] Prescription drugs – including those provided on an outpatient basis as well as physician-administered drugs – play a vital role in cancer care. Over the course of the last few years there has been a remarkable increase in the number of new cancer drug therapies. In 2022, 10 out of the 37 novel drugs approved by the Food and Drug Administration (FDA) were for

[1] Claire Ernst. Virtually all medical groups say payer prior authorization requirements aren't improving. MGMA Stat. March 2, 2022. Available at https://www.mgma.com/data/data-stories/virtually-all-medical-groups-say-payer-prior-autho (reporting that 83% of health care leaders reporting an increase in prior authorization requirements from payers).
[2] American Cancer Society Cancer Action Network. Survivor Views: Affordability, Prescription Drugs, & Pain. December 15, 2021. Available at Survivor Views: Affordability, Prescription Drugs, & Pain | American Cancer Society Cancer Action Network (fightcancer.org).
[3] Centers for Medicare & Medicaid Services. Press Release: CMS proposed rule to expand access to health information and improve the prior authorization process. Dec. 6, 2022. Available at https://www.cms.gov/newsroom/press-releases/cms-proposes-rule-expand-access-health-information-and-improve-prior-authorization-process.

cancer.[4] Yet many patients face burdensome delays in getting these treatments because of prior authorization practices.

Excluding prescription drugs from the modernization provided by the rule undermines the overall success of the API which ultimately rests on its usefulness. Approximately 131 million people (66 percent of adults in the US) use prescription drugs.[5] Excluding prescription drugs from the requirements of the rule will pose an unnecessary burden on providers and patients because they will have to adhere to different timelines and requirements depending on the type of drug and the payer involved. Simplifying the prior authorization process to include prescription drugs will ensure one set of requirements for all prior authorization requests involving health care services.

Prior Authorization Requirements: HHS proposes to require that beginning January 1, 2026, certain payers implement and maintain a Fast Healthcare Interoperability Resources® (FHIR) Prior Authorization Requirements, Documentation, and Decision (PARDD) API to facilitate the prior authorization process. The FHIR PARDD API would reduce the burden of prior authorization requirements on providers. Under this system, providers would be able to submit a query to a payer's system to determine whether prior authorization was required and identify the necessary documentation requirements necessary to complete the prior authorization.

ACS CAN supports the use of this system to better ensure a systematic approach to electronic prior authorization requirements. We believe this approach will help to alleviate provider burden in complying with prior authorization requirements. We also support HHS' decision to implement these provisions on a given date rather than phase in the changes. We agree that phasing in these requirements would be a disservice to providers (who will have to maintain both the API system and their current process).

Reason for denial: HHS proposes that beginning January 1, 2026, impacted payers would be required to provide a specific reason for denied prior authorization decisions regardless of the method used to send prior authorization requests. HHS notes that for prior authorization requests submitted through the PARDD API, in denying a request for prior authorization the payer would have to include information regarding whether the payer approves (and for how long) or denies the prior authorization request or requests more information from the provider to support the request.

ACS CAN supports this proposed policy and, as noted above, strongly urges HHS to require that prior authorization requests concerning drugs also be included. We agree that prior authorization denials are not always specific, resulting in an additional burden on providers and leading to longer waiting periods for patients before they can obtain their medically necessary health care services. We also urge HHS to require that if a prior authorization request is denied, the payer be required to provide specific reasoning for the denial beyond stating that the request "failed to establish medical necessity."

Timeframe: HHS is proposing that beginning January 1, 2026, impacted entities[6] must provide notice of prior authorization decisions as expeditiously as a patient's health condition requires, but no later than 7 calendar days for standard (non-urgent) requests and 72 hours for expedited requests (unless a shorter minimum timeframe is established under state law).

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[4] U.S. Food and Drug Administration. Novel Drug Approvals for 2022. January 10, 2023. Available at https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2022.

[5] Emily Ihara. Profiles: Prescription drugs. Georgetown University Health Policy Institute. Available at https://hpi.georgetown.edu/rxdrugs/.

[6] The proposal would apply this requirement to Medicare Advantage organizations and applicable integrated plans, Medicaid Fee-for-Service programs, and CHIP Fee-for-Service programs. 87 Fed. Reg. at 76296.

ACS CAN supports HHS' intent to standardize the timeframes by which payers should respond to prior authorization requests. We note that state laws regarding timelines for prior authorization requirements vary considerably[7] and imposing a standardized process will limit the burden on providers and patients. As noted above, we also urge HHS to apply these timeframes to prior authorization requests regarding prescription drugs as well.

However, we strongly urge HHS to reconsider the timeframes proposed in the rule and impose more limited timeframes in which payers must respond to prior authorization requests. We are concerned that allowing payers 7 calendar days in which to respond to a prior authorization request can lead to delays in care that can have long-term impact on a patient's overall care. For example, if a provider submits a prior authorization request for a specific biomarker test and does not receive a response for seven business days, the patient is left waiting for more than a week before they can take the test – if it is approved – and then have to wait for the results. The test results help the provider choose the right course of chemotherapy, at which point the provider would have to file another prior authorization request in which to get approval to administer the guideline concordant care. These delays not only impose an undue burden on the provider but can be agonizing and possibly harmful to the patient who is left stuck waiting to begin treatment to fight their cancer.

We also believe the timeframe with respect to expedited requests should be reduced. Seventy-two hours (or 3 calendar days) can be a very long time to wait for approval for an item, service, or prescription drug that meets the requirement of being considered an emergent issue. By definition, an expedited request meets the criteria for being an emergency and requiring an individual to wait 3 calendar days imposes too much of a burden on patients, whose health may be irrevocably harmed by the wait.

We therefore recommend that HHS impose a standard requirement that payers respond to prior authorization requests within 72 hours for non-expedited requests and 24 hours for expedited requests. These standard timeframes are consistent with what we recommend to states, and we believe they will provide patients and providers with more timely determinations.

The proposed rule does not seek to change prior authorization timeframes for QHPs on the Federally-facilitated exchanges. We urge HHS to reconsider and to require standardized timeframes under which all payers should respond to prior authorization requests.

HHS does not propose recourse for providers and patients when the payer fails to meet the prior authorization timeframes. Rather, in such instances HHS recommends that providers contact the payer to obtain the status of the request. We strongly urge HHS to implement penalties for payers who fail to adhere to the prior authorization timeframes. HHS should monitor the extent to which payers are failing to meet their prior authorization timeframes and consider taking administrative action against those plans that have an unacceptably high rate of failing to meet timeframe standards.

Public reporting of prior authorization metrics: HHS proposes that impacted payers would publicly report certain aggregated metrics about prior authorization by posting them directly on the payer's website. HHS proposes that the reporting would be at the organizational level for Medicare Advantage organizations, the state level for Medicaid and CHIP FFS, the plan level for Medicaid and CHIP managed care, and the issuer level for QHP issuers on the FFEs. Metrics to be reported include all items and services that require prior authorization; percentage of prior authorization requests (both standard and expedited) that were approved (aggregated for all items and services); percentage of prior authorization requests that were approved after appeal (aggregated for all items

[7] American Medical Association. 2021 Prior Authorization State Law Chart. Available at https://www.ama-assn.org/system/files/2021-04/pa-state-chart.pdf.

and services) and the median time that elapsed between the submission of a request and the determination by the payer.

ACS CAN supports the public reporting of prior authorization metrics. As noted above, we strongly urge HHS to also amend the rule to cover prior authorization requests related to prescription drugs and data with respect to these prior authorization requests should also be included in HHS' proposed metrics.

We believe in addition to having this information be located on the payer website, that CMS be required to publish this information as well on pages of its website which correlate to a particular payer. For example, the information on Medicare Advantage organizations could be found on the CMS website related to Medicare plans and on the Plan Finder.

With respect to the level of reporting, we believe that payers should be required to report data at the plan level and not at the issuer level. People enroll in individual health plans and health plan responsiveness can vary even among the same issuer. Reporting information at the plan level will also make it easier for HHS to determine which plans are in compliance with prior authorization requirements and for which plans additional oversight may be necessary.

We urge HHS to require payers to report prior authorization metrics not on an aggregated basis for all items and services, but rather to report data based on categories of items and services (e.g., prescription drugs, hospitalizations, laboratory services, etc.). Information aggregated across all items and services will fail to inform whether the payer is imposing prior authorization requirements inappropriately for given services. Requiring payers to report based on category of services will provide a more accurate reflection of how the payer is using the prior authorization process and could show, for example, if a payer has a higher than average percentage of prior authorization requests that were overturned for imaging services compared to hospitalizations.

III. Request for Information

A. Request for Information: Accelerating the Adoption of Standards Related to Social Risk Factor Data

HHS requests information and input on the barriers to using industry standards for social risk data collection and opportunities to increase the adoption of such standards.

ACS CAN supports HHS highlighting the impact of social risk factors on health outcomes and generally supports funding and policies that promote the timely collection and publication of demographic data that aid researchers and policymakers in identifying disparities to improve health equity in cancer prevention, detection, and treatment. Research shows how differences in social determinants of health—the conditions in the places where people live, learn, work, and play—are associated with profound inequities in cancer incidence, care delivery, and patient outcomes, including stark disparities in survival. More than one in five patients with cancer in the United States struggles to meet housing, transportation or food security needs, and estimates are much higher for patients from historically marginalized populations including Black and Hispanic individuals, as well as individuals living in poverty.[8] These social risk factors are associated with delays in cancer diagnosis and initiation of cancer-directed therapy, greater distress and financial toxicity, and a higher risk of relapse and death.

ACS CAN encourages HHS to collect data on social risk factors, which will not only help identify the barriers that certain groups face in accessing care but would also be helpful to target cancer prevention and control efforts – potentially helping health systems develop screening measures and prevention programs that would better

[8] Bona, K., & Keating, N. (2022). Addressing Social Determinants of Health: Now Is the Time. JNCI: Journal of the National Cancer Institute, Volume 114, Issue 12, December 2022, Pages 1561–1563, https://doi.org/10.1093/jnci/djac137.

identify diagnoses at earlier stages when less invasive and less costly treatment options are available to patients. However, data on social risk factors can be difficult to collect across different formats, potentially creating a burden on patients, providers and the healthcare system overall by creating duplications or inefficiencies in managing referrals for social services and conflicting workflows in an already strained system. HHS should be mindful of these challenges so as not to impede opportunities to provide high quality care and data, potentially resulting in missed opportunities to address the root causes of poor health outcomes and health inequities.

CONCLUSION

Thank you for the opportunity to comment on the proposed rule related to interoperability and improvements with the prior authorization process. 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.

Sincerely,

Lisa A. Lacasse, MBA
President
American Cancer Society Cancer Action Network