NATIONAL ASSOCIATION OF Community Health Centers

March 6, 2023

Administrator, Chiquita Brooks-LaSure
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW, Room 445-G
Washington, DC 20201

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)

The National Association of Community Health Centers (NACHC) is the national membership organization for federally qualified health centers (also known as FQHCs or health centers). Health centers are federally-funded or federally-supported nonprofit, community-directed provider clinics that serve as the health home for over 30 million people, including 1 in 5 Medicaid beneficiaries and over 3 million elderly patients. It is the collective mission and mandate of over 1,400 health centers around the country to provide access to high-quality, cost-effective primary and preventative medical care as well as dental, behavioral health, and pharmacy services and other "enabling" or support services that facilitate access to care to individuals and families located in medically underserved areas, regardless of insurance status or ability to pay.

Health centers serve some of the nation's most vulnerable patients; nearly 70% of health center patients live under 100 percent of the Federal Poverty Level (FPL) 91% live under 200 percent FPL. Additionally, 79 percent of health center patients are uninsured or publicly insured.[1] Health center patients have complex care needs, and health centers provide care coordination to better achieve whole-person care and connect patients to the care they need. The prior authorization process has unfortunately served as a barrier to access to care for many patients and served as bureaucratic red tape for providers trying to best meet their patients' needs. NACHC supports many of the proposals in this proposed rule because of their intent to increase the efficiency of the prior authorization process by making it electronic. The standardization of the process across payers will cut down on the cumbersome process health centers have faced when trying to comply

[1] https://www.nachc.org/wp-content/uploads/2022/03/Chartbook-Final-2022-Version-2.pdf

with differing prior authorization processes and forms. NACHC is appreciative of these proposed changes that will provide clarity for both the patient and the providers on the process, and are hopeful these changes will result in enhanced access to care for patients.

NACHC welcomes the opportunity to comment on the Advancing Interoperability and Improving Prior Authorization Processes Proposed Rule and will focus our comments on the areas most important to FQHC patients and providers. Our comments are broken into three sections: I. Patient Access API; II. Provider Access API; and III. Improvements to the Prior Authorization Process.

I. Patient Access API

NACHC is supportive of the proposals surrounding directing impacted payers[2] to include specific prior authorization information available to patients via a patient access application program interface (API). The current prior authorization process varies from state to state and payer to payer. The oftentimes opaque process can leave the patient wondering about the status of their prior authorization. A 2021 survey of 1,000 physicians demonstrates how archaic the prior authorization process has been despite our society's technological advancements. Fifty-eight percent reported that phone calls with insurance companies were often or always required for prior authorization requests for prescriptions, and 59% reporting this true for prior authorization for medical services. Nearly 50% reported faxing were always or often necessary for prescriptions, and 46% reported this was true for medical service requests.[3] This process puts undue burden on the provider and does not include the patient. NACHC applauds the agency for building upon prior rulemaking[4] by including prior authorization in the Patient Access API. Having this prior authorization information available electronically can empower patients and involve them more in their care plan.

NACHC supports that health care items and services be subject to the electronic prior authorization process for both the Patient Access API and the Provider Access API. For future rulemaking, NACHC recommends CMS work with different agencies such as ONC and SAMSA, along with states, to make prescription drugs subject to these prior authorization requirements and be included in these APIs. While we understand that the processes and standards for prior authorization differs for prescription drugs, patients deserve the same transparency in the prior authorization process when it comes to their prescriptions.

The number of required prior authorizations for prescription drugs has increased over the years, according to 84% of physicians per a 2021 survey.[5] This trend has been consistent at health centers, which have seen an increase in prior authorization for higher-cost brand drugs versus generic

[2] Medicare Advantage Organizations and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-facilitated Exchanges
[3] https://www.ama-assn.org/system/files/prior-authorization-reform-progress-update.pdf
[4] https://www.govinfo.gov/content/pkg/FR-2020-05-01/pdf/2020-05050.pdf
[5] https://www.ama-assn.org/system/files/prior-authorization-reform-progress-update.pdf

drugs. This becomes an issue for patients who cannot take the generic alternative or if the generic is unavailable due to pharmaceutical storage. Furthermore, chronic medications constantly trigger prior authorization when a patient requires a refill. Instances like these showcase the need for prescription drugs to be subject to these same provisions aimed at enhancing and improving the prior authorization process.

Health centers take pride in offering pharmacy services and contract with community pharmacies to expand patient access to affordable prescription drugs. Many health center pharmacies employ clinical pharmacists who ensure that providers are kept up to date with the latest prescriptions on the formulary, so providers can make an informed choice on what is best for the patient's condition. Clinical pharmacists also ensure patients understand their medication and lend themselves as a resource for any patient follow-up questions. NACHC encourages CMS to include prior authorizations for prescription drugs within the scope of this proposed rule to improve care coordination for patients by improving interoperability between providers and pharmacists. It is crucial to include prescription drug prior authorization in the Patient Access API.

The decline in available medications in the 340B Drug Pricing Program is a huge issue as well for health centers and ties back to prior authorization. Since 2020, pharmaceutical manufacturers have refused to ship 340B-priced medications to contract pharmacies that expand the reach of health centers. These restrictions have left providers and subsequently their patients with fewer choices for affordable prescription drugs – patients either must pay hundreds of dollars for the same medication, or switch to a potentially less effective medication. Health centers do offer copay assistance programs but discounts through the 340B program are crucial for patient savings on high-priced drugs.

Furthermore, Pharmacy Benefit Managers (PBMs) have taken advantage of the lack of federal oversight on their participation in the 340B program. PBMs determine which pharmacies will be included in a prescription drug plan's network and how much said pharmacies will be paid for their services. As PBMs increase the numbers of drugs excluded from formularies, providers cannot see in real time which drugs are subject to prior authorization or have information about alternatives.[6] Including prescription drugs in electronic prior authorization is crucial in enhancing provider knowledge about which drugs are subject to prior authorization and can get better real-time results. If not, the onus is placed on the patient to navigate prior authorization process by trying to determine which drugs are both affordable and covered.[7] NACHC encourages transparency on the prior authorization process extend to prescription drugs as well for the API.

[6] https://www.managedhealthcareexecutive.com/view/why-states-are-allowing-pharmacies-to-dispense-returned-oncology-drugs

[7] https://www.managedhealthcareexecutive.com/view/why-states-are-allowing-pharmacies-to-dispense-returned-oncology-drugs

NACHC appreciates the details on what information is required to be available through the Patient Access API. Details about the prior authorization status, the approval/denial date, the date or circumstance under which the authorization ends, the items and services approved, and the quantity used to date under the authorization all help the patient track their prior authorization. We also support requiring payers to cite a specific reason in the event of a prior authorization denial, to ensure that both patients and providers understand the rationale behind a denial, including documentation. This can help in the event the provider and patient decide to appeal the decision. NACHC strongly supports CMS' intention to enhance transparency around the prior authorization prior which helps patients better engage with their health care.

Ensuring that prior authorization information is available for up to at least a year after the last status is important for health center patients and NACHC supports this provision. Having this data easily accessible will help health centers, which serve a large transient population. In 2020, health centers provided care to 1.3 million patients experiencing homelessness and over 1 million agricultural workers.[8] These patients are more likely to move frequently, making it more difficult for them to keep track of any outstanding prior authorization requests Health centers have a short window of time to provide care because these patients may not come back months at a time so keeping this information for longer makes it easier to maintain the continuum of care. Furthermore, given that this information will be available to their providers through the Provider Access API, this helps future providers understand the patient's current health status more quickly and better meet their care needs.

NACHC appreciates CMS' intention to ensure patients receive adequate education resources regarding the Patient Access API by directing payers to develop those resources and recommend the agency review past educational resources about the Patient Access API to meet health center patient needs. With over 14,000 individual sites across the U.S., health centers serve a large patient population who speak various languages. Nearly a quarter of health center patients are best served in a language other than English. Additionally, limited access to reliable technology (e.g., internet and computers), as well as a low health and digital literacy, may restrict a health center patient's ability to engage meaningfully with the API. NACHC understands that the agency directed payers to provide educational resources to their current and former patients with information to help protect the privacy and security of their health information in the *Interoperability and Patient Access final rule*. We recommend CMS revisit the educational materials developed to ensure that information about the Patient Access API given to health center patients are crafted and disseminated in ways that best meets the population's unique needs.

NACHC supports CMS' proposal to require impacted payers to report aggregated, de-identified data metrics to CMS annually on how patients use the Patient Access API. This will help the agency identify ways to improve the Patient Access API and see overall usage trends on key features of the API. While these data will not be available publicly, we support CMS'

[8] https://www.nachc.org/wp-content/uploads/2022/03/Chartbook-Final-2022-Version-2.pdf

intention to include them in subsequent reports about the Patient Access API. We also believe that in future rulemaking, CMS should require payers to included aggregated demographic information, as well as other quantitative measures. Data on patterns of API utilization by company/endpoint, type of access/use, and frequency of use would help paint a clearer picture of usage uptake of the Patient Access API. Besides those data, we support the idea of mandating payers report demographic data in future rulemaking. These data will help inform CMS where the gaps are in usage of the Patient Access API and help them strategize on how and where to increase uptake. Knowledge of this data can better help the agency ensure health equity for vulnerable communities by taking steps to confirm these communities are able to access all their data via the Patient Access API and be better informed of all their health information, including prior authorizations.

Furthermore, NACHC strongly recommends that measures of API functionality and usability are required for vendors, payers, and health care organizations who provide patient access. Terabytes of data are being transmitted daily in health care; however, we know that much of these data are not used in practice because it was not made directly visible to users and cannot be incorporated into the product or record. NACHC recommends that CMS tracks how many requests to an API were successful and how many were rejected because of issues with authorization or a malformed query as well as how many calls from the API were not received by the requestor. Finally, understanding metrics of how many calls are made per query, how many queries were made per user and what the cost of maintaining the API was per call would help systems and patients to understand which APIs are providing added value to patients. With these data, CMS can analyze trends to identify any disparities in patient access to health data and implement policies to mitigate these disparities to better meet patient needs.

NACHC generally agrees with all the proposals in this provision but recommends that out-of-network providers also be included in the Patient Access API. Given varying network adequacy standards, a patient may seek need to seek care from an out-of-network provider. For instance, Medicaid Managed Care plans have wide discretion for measuring provider network adequacy. States currently calculate these standards quantitatively, given that the 2020 CMS Medicaid managed care final rule removed the state requirement of using time and distance standards.[9] These changes do not take into account geographic and distance barriers health center patients may face in getting access to timely care. The nearest provider who accepts Medicaid may not be in the patient's insurance network. Health center patients should be able to access prior authorization information via the Patient Access API no matter their provider, and their provider should be able to offer the same services for prior authorization despite their network status with the patient.

[9] https://www.federalregister.gov/documents/2020/11/13/2020-24758/medicaid-program-medicaid-and-childrens-health-insurance-program-chip-managed-care

This network adequacy issue can also arise when FQHCs contract with Quality Health Plans. NACHC appreciate CMS' proposal in the 2024 Notice of Benefit and Payment Parameters proposed rule to increase the percentage of FQHCs that QHPs must contract with to 35%, given their status as Essential Community Providers. FQHCs are the largest single source of primary care in medically underserved areas and for medically underserved populations. They provide all the necessary health services to help ensure their patients can live healthier lives and increase their overall well-being. However, there is currently no mechanism to allow the Department to monitor and enforce QHP compliance with the federal ECP standard and partner with state-based Marketplaces to ensure that plans, including managed care plans, across the nation meet the ECP participation standard. Stronger oversight and enforcement will ensure that families will have adequate access to affordable, quality care provided by health centers, located within their own communities. Without oversight and enforcement, network adequacy may not be sufficient for every health center patient.

Instances like these with Medicaid Managed Care and QHPs show the importance of the Patient API and Provider API extending to all providers, regardless of their network, for patients for prior authorization. Patients should be able to have access to the same prior authorization information regardless of where they receive their care for specific services. It is imperative to keep providers informed about patients under the care, no matter if they are in or out of the patient's network. Patients having access to prior authorization decisions for prescription drugs is also important for their care.

II. Provider Access API

NACHC is supportive of CMS efforts to improve interoperability and enhance access to patient care records, including electronic prior authorization. We appreciate that all the details related to electronic prior authorization listed in the previous section – related to its status, items/services listed, as well as the decision— will also be available for the provider via the Provider Access API. **As CMS finalizes the specific provisions of this proposed rule, NACHC requests that the unique needs of health centers and other safety net providers be taken into consideration to ensure a successful uptake in the Provider Access API.**

NACHC's member health centers (FQHCs and look-alikes) and partner organizations Primary Care Association (PCA) and Health Center-Controlled Networks (HCCN) are the largest national primary care network providing high quality culturally responsible care to the nations underserved. HCCNs are groups of health centers working together to use health information technology (health IT) to improve operational and clinical practices. HCCNs help health centers leverage health IT to increase participation in value-based care by enhancing the patient and provider experience, advancing interoperability, and using data to enhance value. They provide specialized training and technical assistance to take advantage of economies of scale, including group purchasing power, shared training, and data analytics. In 2021, approximately 83% of federally funded health centers participate in an HCCN, an increase from approximately 73% over the past 3 years.

HCCNs also provide support services for the sharing of data through health information exchanges (HIEs) and APIs, as well as support services for data privacy and security. HCCNs have a long and successful track record for improving health center operations. They have developed infrastructures and expertise needed to support their mission driven health center members in improving population health while reducing costs, and while prioritizing patient experience and care team well-being. HCCNs are a critical component to health center interoperability and to the successful, meaningful sharing and utilization of health center patient data. Some HCCNs are also PCAs, serving an entire state's worth of FQHCs.

NACHC supports CMS' proposals to require payers to provide educational resources with patients as well as providers on the Provider Access API. For patients, it is crucial that these resources are in easy-to-understand terms and does not include confusing jargon. NACHC recommends that CMS to consult with HCCNs when developing and disseminating educational materials on the Provider Access API. This partnership will ensure the guide can be tailored to the specific needs of health center providers and best meet patient needs in understanding how their data is being used in the Provider Access API and their opt-out rights.

We appreciate the possibility that States operating Medicaid and CHIP programs might be able to access federal matching funds to support implementation of Provider Access API; NACHC requests that CMS ensure safety net providers be prioritized in receiving these funds if they are available. Safety net providers, like health centers, operate on thin margins and would greatly benefit from additional funding to help costs such as provider training and implementation costs. In response to the unique needs of their patients, health centers invest significant resources into training for their staff and patients to meet meaningful use and interoperability requirements. CMS should consider the specific investments that health centers make including the cost, administrative set up, staff and clinical training and patient education needed to ensure appropriate interoperability and access.

NACHC understands CMS' rationale for the importance of developing a patient attribution system. **However, we recommend CMS align patient attribution requirements and processes among the same payer and work with other agencies, such as CMMI, to see where patient attribution strategies can be better streamlined across payers.** Patient attribution helps identify the health care relationship between the patient and provider. Successful patient attribution is crucial to success in value-based care (VBC) arrangements, for instance,[10] and CMS has strongly encouraged health care providers, including FQHCs, to increase their participation in these arrangements. In partnership with their state PCAs and HCCNs, health centers across the country have already been actively engaged in Accountable Care Organizations (ACOs) and the Medicare Shared Savings Program. In 2021, 15 states had FQHCs that lead ACOs.[11] Some health centers participating in these VBC arrangements have reported issues with the patient attribution system.

[10] https://www.soa.org/493462/globalassets/assets/files/resources/research-report/2018/patient-attribution.pdf
[11] NACHC 2021 PCA Policy Survey Assessment

One PCA stated that of their health centers participating in VBC arrangements, between 20% to 40% of patients that have been attributed are established with their health center, depending on the payer. If not correctly attributed, this could place undue administrative burden on providers who cannot access prior authorization data for their patients, ultimately hurting the patient's access to care. Furthermore, incorrect attribution can hurt overall care coordination efforts. The linkage between patient attribution and provider care necessitates better alignment; NACHC encourages CMS to align patient attribution requirements and processes among the same payer to decrease provider burden.

III. Improvements to the Prior Authorization Process

We appreciate the proposal for payers to implement the Prior Authorization Requirements, Documentation, and Decision (PARDD) API so providers can see which items and services may be subject to prior authorization and identify documentation requirements. This will help decrease provider burden by ensuring providers can preemptively gather documentation, hopefully expediting the prior authorization approval process. One PCA noted their health centers saw a spike in prior authorizations for imaging services such as MRIs and CT scans, specifically with Medicaid. Another PCA relayed that their health centers saw an increase in prior authorizations for some behavioral health services, such as 60-minute visits. The PARDD API has the potential to alleviate provider burden in instances like these by providing transparency about which services may be subject to prior authorization.

We are also encouraged that the PARDD API would allow payers to share with providers the status of the prior authorization request and whether the request has been approved or denied. NACHC reiterates the importance of including prescription drugs in these proposals, including the PARDD API, given that providers have seen a dramatic increase in prior authorizations for prescription drugs. Having access to what documentation may be needed or which drugs are subject to prior authorization would enable providers to make better judgement calls when helping their patients. Lack of information on prescription drugs could create a chilling effect on providers recommending certain prescriptions as well. We recommend CMS extend these positive PAARD API proposals to include prescription drugs, as this would expedite the entire prior authorization process as well.

NACHC supports the proposal to expedite the prior authorization process for standard requests, cutting it in half from 14 days to 7 days. We believe this is a step in the right direction for increasing timely health care access for patients. We encourage CMS to consider alternatives for both expedited and standard requests for prior authorizations, as mentioned in the proposed rule. CMS' example of 48 hours (versus 72 hours) for an expedited prior authorization, and 3 days for standard requests, would help alleviate any delays in care for patients. One survey of more than 1,000 physicians found that over 93% of those surveyed said prior authorization led to delayed patient access to crucial care.[12] Health center patients are particularly vulnerable and delays in care

[12] https://www.ama-assn.org/system/files/prior-authorization-survey.pdf

can result in adverse health outcomes. These timeliness standard changes, unfortunately, will not apply to QHPs on the Federally Facilitated Exchanges; we urge CMS to reconsider and align these standards. What type of insurance a patient has should not negatively impact timeliness for prior authorization processes, which could result in delays accessing care. NACHC is supportive of ways to decrease the amount of time it takes to process prior authorization and overall decrease instances of prior authorization. Along this same vein, there should be standardization on the appeals process.

NACHC urges CMS to recommend a standardization around the appeals process for payers. If a prior authorization request is denied, payer protocol oftentimes dictates that providers complete a peer-to-peer review. This process requires physicians to discuss the need for a specific procedure or drug with another physician in the payer's network to obtain prior-authorization or reverse a denial of a prior authorization.[13] While well-intentioned, it can take significant provider time to not only schedule the peer-to-peer review but then complete it. This administrative task takes valuable provider time away from patients, resulting in decreased patient access. The appeals process currently varies from payer to payer. Improper denials can lead to high out-of-pocket costs for patients or can lead to patients not seeking care altogether. NACHC strongly recommends streamlining and standardizing the appeals process to reduce provider confusion and decrease patient delays in care.

To further decrease instances of care delays, NACHC also recommends implementing a timeliness requirement for payers to respond to an appeal, in the event of a prior authorization denial. There is often a quick turnaround time required between a denial and a provider completing this peer-to-peer, yet there are disparate timeframes imposed on the payer to make a decision after a provider appeals a prior authorization denial.[14] CMS should work with different payer stakeholders to create timeliness standards in responding to appeals to decrease delays in patient access to care.

NACHC also recommends that CMS put out guidance to payers on what defines a standard prior authorization versus an expedited prior authorization. The lack of common definition leads to discrepancies on what a payer considers "urgent" and sometimes leaves some discretion up to the provider. This lack of standardization can adversely affect a patient. If a payer has a stricter definition of what constitutes an expedited prior authorization, this could lead to the patient waiting up to 7 days for a decision, and delay access to care further if prior authorization is denied. CMS should release guidance on definitions to facilitate more alignment for payers and strengthen patient access by minimizing variation between network standards on what is considered "urgent" versus "normal."

[13] https://www.ama-assn.org/practice-management/prior-authorization/how-make-peer-peer-prior-authorization-talks-more-effective

[14] https://www.ama-assn.org/system/files/2021-04/pa-state-chart.pdf

To ensure prior authorization timelines are being met, NACHC supports the proposals to require payers to publicly report prior authorization metrics. Having metrics available such as the percentage of approvals and denials for both standard and expedited requests could help cut down on the items and services subject to prior authorization. Additionally, publishing the average time elapsed between submission and decision of prior authorization will also help payers remain accountable to the standards in place when these regulations are finalized. We also recommend CMS put out guidance on how to best address instances if payers do not abide by the published timeline requirements. Currently, the burden falls on the provider to follow-up with the payer if prior authorization requests are not addressed. This process takes significant time, and the provider should not be responsible for holding payers accountable for compliance. NACHC also believes these prior authorization metrics these data will help inform policies such as gold-carding for providers.

NACHC is supportive of CMS' stated encouragement to payers to adopt gold-card approaches to allow certain providers who have demonstrated compliance with prior authorization requirements to receive exemptions or more streamlined reviews. We recommend CMS put out guidance formally recommending payers to implement gold card type initiatives and ensure that gold carding privileges extend to all items and services for eligible providers, not just specific service categories. This will ensure that providers and their patients will experience the full benefits of this strategy to decrease unnecessary prior authorizations. Gold-carding would help decrease the amount of time staff and providers would need to spend on prior authorization. Prior authorization is an expensive process for health care organizations that in many cases significantly restricts patients' ability to access needed care.[15] It can take weeks to adjudicate the request, resulting in costing hundreds of dollars in staff and provider time at a health care organization for a single therapy for a single patient. Notably, this effort is not reimbursed and takes valuable staff resources. Health center patients often have less comprehensive health insurance plans that demand more frequent prior authorization than other plans for higher income patients. Prior authorizations can exacerbate health care inequities for patients while also increasing the burden of cost for prior authorization on health centers who already provide lower cost care with fewer resources. Gold-carding would decrease these burdens and NACHC supports gold-carding as a strategy to enhance patient access to care.

Thank you for your consideration of these comments. We are supportive of these provisions that will advance electronic prior authorization, increase timely access to care, and promote overall interoperability standards that will greatly benefit patients. If you have any questions, please contact Vacheria Keys, Director of Policy and Regulatory Affairs, at vkeys@nachc.org.

Sincerely,

[15] https://www.fiercehealthcare.com/practices/costs-prior-authorizations-increase-for-physician-practices-at-alarming-rate

Sincerely,

Joe Dunn

Senior Vice President, Public Policy and Research

National Association of Community Health Centers