AMERICAN ACADEMY OF FAMILY PHYSICIANS

March 10, 2023

The Honorable Xavier Becerra
Secretary
Department of Health and Human Services
200 Independence Ave SW
Washington, DC 20201

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

**Re: CMS-0057-P: 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**

Dear Secretary Becerra and Administrator Brooks-LaSure:

On behalf of the American Academy of Family Physicians (AAFP), representing more than 129,600 family physicians and medical students across the country, I write in response to the proposed rule regarding advancing interoperability and improving prior authorization processes as published in the Federal Register on December 13, 2022.

The AAFP appreciates the Centers for Medicare and Medicaid Services (CMS) introducing proposals to improve the electronic exchange of health care data and streamline prior authorization processes. Prior authorization processes cause barriers to care, delay care for enrollees, and impose significant administrative burdens on physicians. We applaud CMS for consulting with stakeholders ahead of the development of this updated proposed rule, as well as for including Medicare Advantage in the list of impacted payers in this proposed rule, consistent with previous AAFP advocacy.

A 2022 report from the Department of Health and Human Services (HHS) Office of Inspector General (OIG) confirmed that Medicare Advantage (MA) plans sometimes deny prior authorization and payment requests that meet Medicare coverage rules by using clinical criteria not in Medicare coverage rules and requesting unnecessary documentation, as well as making errors. Among the denials analyzed by OIG in the report, 13 percent met Medicare coverage rules and should have been approved. Denials of prior authorization requests that should have been approved impose significant negative effects on beneficiaries. Not only can inappropriate denials delay or prevent access to care and cause beneficiaries to pay out of pocket for services that should be covered, but it also adds a significant administrative burden on physicians and their patients to appeal these denials. In addition to enrollees in MA plans, enrollees in other health plans needing care for their own chronic illness,[i] their children's chronic illness,[ii] and rare diseases[iii] have experienced barriers to care from prior authorization requirements. In 2022, California-based L.A. Care, which administers Medicaid and other types of coverage, failed to address a backlog of more than 9,000 prior authorization requests and more than 67,000 complaints or appeals.[iv]

Further, evidence indicates that prior authorization requirements may be discriminatory and worsen health disparities, as documented in a study examining access to treatment[v] for HIV pre-exposure prophylaxis and a white paper[vi] which examined the disproportionate impact of prior authorization requirements on cardiovascular care for Black patients and other patients of color.

**The AAFP agrees with CMS that guardrails are necessary to ensure UM processes like prior authorization are used appropriately and ensure timely access to medically necessary care, rather than inhibit patient access to care.** Physicians have noted that prior authorization requirements are continually increasing, taking time away from providing quality care to their patients and imposing significant, time-intensive and cumbersome administrative tasks on physicians and their staff, which also contributes to burnout. According to an American Medical Association (AMA) survey, 85 percent of physicians report that the burden associated with prior authorization is "high" or "extremely high" and 30 percent of physicians report that prior authorization has led to a serious adverse event for a patient in their care. The survey reports that physicians and their staff spend almost two business days each week completing an average of 40 prior authorizations per physician, per week.

The AMA survey also highlights the impact of prior authorization on patients: 90 percent of physicians say that prior authorization somewhat or significantly impacts patients' clinical outcomes. Furthermore, 79 percent of physicians report that issues related to prior authorization can at least sometimes lead to patients abandoning their recommended course of treatment while 94 percent of physicians report care delays associated with prior authorization. These delays increase wait times for medical services and prescriptions for patients while diminishing access to timely care. Further, a study of physician time in ambulatory practice across four states and several specialties reports physicians spend 27 percent of their total time on direct clinical face time with patients and almost 50 percent of their total time on electronic health record (EHR) and desk work, which includes working through prior authorization requests with plans.[vii] Taken together, evidence demonstrates that prior authorizations are causing care delays, worsening patient outcomes and satisfaction, and are a significant driver of administrative burden and physician burnout.

The AAFP is strongly supportive of the provisions in this proposed rule, however, automating prior authorization is just one step in reducing the care delays and administrative burdens resulting from prior authorization. **Comprehensive reform and a reduction in the overall volume of prior authorization requests is necessary to see a meaningful reduction in the harmful impacts of prior authorization on patient care and physician wellbeing. The AAFP strongly urges CMS to swiftly implement additional guardrails, transparency requirements, and other reforms across payers to more comprehensively address the negative impacts prior authorizations are having on patients and physicians.** We recently submitted comments supporting proposals to address the inappropriate denials of prior authorizations in Medicare Advantage and urging CMS to expand upon these proposals. We urge similar expanded action across payers.

We are pleased to see CMS considered and incorporated stakeholder feedback in response to previous rulemaking in this area, including the AAFP's recommendation to apply these requirements to MA plans. MA enrollees should have equitable access to their health care data, as well as be able to benefit from streamlined prior authorization processes and timelines. Applying these requirements to MA plans will be helpful in standardizing prior authorization across more payers and reduce the administrative complexity of dealing with different plan requirements. Additionally, this standardization across plans makes the investment in updates and adoption of new standards more worthwhile for physician practices.

However, the AAFP is concerned and disappointed these proposals do not apply to prior authorizations for prescription and outpatient drugs. Drug prior authorizations are a significant issue for patients and physicians. Family physicians report that prior authorization requirements for medications are the most burdensome and excluding them from the required standards and APIs will severely limit the impact this rule will have on improving patient care or reducing administrative burdens. **The AAFP strongly urges CMS to expand the proposals in this rule to Medicare Part D plans and prescription drug coverage across other impacted payers.**

Application Programming Interfaces (APIs), messengers that help different software programs communicate with each other, are helpful technology to support an easier exchange of health information between different software. Patients use APIs to access their patient portals, which pull information from their physician's electronic health record (EHR) system, giving patients secure access to their health information. The AAFP is supportive of the use of APIs to both improve patients' access to their health information and facilitate secure information exchange across a patient's care team. **However, the AAFP strongly believes any standards for such APIs must undergo robust real-world testing in a variety of clinical settings, including small, independent, and rural physician practices, and with all end-users, including physicians, to ensure standards are effective, adoptable, and efficient.** Only with end-user engagement and feedback should standards be considered mature or mandated for use, and the AAFP encourages CMS to apply this approach to the proposals in this rule.

The AAFP requests CMS provide clarity in the final rule about how the information shared in each of the proposed APIs will interact with information blocking and HIPAA regulations. Additionally, we urge CMS to work with ONC, Congress, and industry stakeholders to advance a data privacy framework that protects patients' health data once it is in the hands of an entity that is not covered by HIPAA. While the AAFP strongly supports efforts to promote interoperability and patients' easy access to their health information, the continued advancement of APIs and proliferation of third-party applications also increases privacy and security risks. Additional federal action is needed to safeguard patient privacy and data security outside of HIPAA.

**Patient Access Application Programming Interface (API)**

CMS is proposing to require Medicare Advantage (MA) organizations, state Medicaid and Children's Health Insurance Program (CHIP) fee-for-service programs, Medicaid and CHIP managed care plans, and qualified health plan issuers (referred to throughout our comments as "impacted payers") to provide patients with access to information about the prior authorization requests and decisions, related administrative and clinical documentations, and the specific reason for any denial of a request made for their care through the already established Patient Access API. CMS also proposes to require impacted payers to report annual metrics to CMS about patient use of the Patient Access API.

**The AAFP supports this proposal to promote patient access to their information, including information about active, pending and denied prior authorization requests via the Patient Access API.** The AAFP supports policies, including the Patient Access API, that improve patients' access to their health information, involve patients in their care, and make information about prior authorizations readily available to patients, which could promote transparency and reduce patients' frustration with physicians when care delays arise. Even though payers require and fulfill PAs, family physicians often report they and their staff bear the brunt of patients' frustration with PAs and the associated care delays. We believe allowing patients to see the status of their PAs may help alleviate some of the added burden on physicians and their staff.

Patient access to their electronic health information largely occurs through patient portals, however, not all patients are aware of the option to use a patient portal, may struggle to access their portal, or avoid using it altogether. Unfortunately, there exist racial and ethnic disparities in patient portal use. A recent study from the Office of the National Coordinator for Health Information Technology (ONC) found that Black and Hispanic individuals were offered and accessed patient portals at significantly lower rates than white individuals, with the disparity mostly being that these patients are not offered a patient portal.[viii] When examining access and use among those who reported being offered a portal, disparities largely diminished and those who were offered a portal and encouraged by their physician to use it were more likely to access it. **The AAFP encourages CMS to develop educational and training materials for patients and clinicians and partner with payers to work with plans and health care organizations to eliminate disparities in patient portal offers and use of health apps to ensure patients benefit equally.**

CMS requests comment on whether they should consider policies to require impacted payers to include information about prior authorizations for drugs, when the payer covers drugs, via the Patient Access API, Provider Access API, and Payer-to-Payer API. CMS also requests comment on how they can help give patients the tools they need to understand the privacy and security implications of using a health app within the scope of their regulatory authority.

**The AAFP strongly encourages CMS to apply all proposals in this rule to Medicare Part D plans and prescription drug coverage across other impacted payers.** Prior authorizations are regularly required by payers to prescribe and administer prescription and outpatient drugs. Excluding them from the required standards and APIs severely limits the impact that this rule will have on patient care or administrative burden. Further, given that CMS is proposing payers and health care organizations share protected health information with non-covered entities, including third-party health apps, without any restrictions to protect the patient's privacy, it should be the responsibility of CMS to educate patients, not payers and health care organizations.

**Provider Access API**

CMS is proposing to require impacted payers to build and maintain a FHIR-based Provider Access API to share patient claims and encounter data (excluding cost information), data elements identified in the United States Core Data for Interoperability (USCDI) version 1, and prior authorization requests and decisions with in-network providers with whom the patient has a treatment relationship. CMS proposes to require payers to provide a mechanism for patients to opt out of making their data available to providers through this API.

**The AAFP supports this proposal and recommends that such APIs use specific standards across all payers.** The AAFP supports the use of FHIR Bulk Data Access, which should allow physicians to request data on all their patients that are members of a specific payer. Research shows that patients achieve better outcomes when their record is more complete and there is more data available to the health care provider at the point of care.[ix] We encourage CMS to be mindful of the cost to physician practices, particularly small, independent, and rural practices, of updating and implementing this API and how this may lead to varied timelines of adoption and use across all clinical settings. When implemented, the AAFP encourages CMS to ensure this information is available at the point of care to achieve more transparency between physicians and patients and a more tangible reduction in burden.

The AAFP is supportive of the opt out policy rather than opt in. Most patients want their health information shared with their physician. In a recent study on patients accessing and sharing their

health data, 81 percent of respondents said providers should be able to share health data about patients they have in common, particularly for patients' clinical records, lab results and radiology images and reports, personal medical history and family medical history, and physician and clinical notes.[x] Many of these components are individual characteristics of patients that inform future treatment plans that may be subject to prior authorizations. The AAFP has long supported policies that guarantee the appropriate security of protected health information while working to improve patients' access to their data, as well as the ability to share patients' health information across the care team. Improved sharing of this data leads to optimal coordination across the care team, improved trust and confidence between a patient and their clinicians, and in turn, improved health outcomes.

We appreciate CMS including requirements for payers to develop informational and educational resources on the benefits, patient rights, and instructions for both patients and providers about the Provider Access API. **CMS should not rely on physicians to educate patients on the intricacies of APIs. The AAFP encourages CMS to provide standardized language and guidelines to plans around how the process to opt out will be communicated to patients and the process for collecting and communicating opt outs to physicians.** We encourage CMS to develop a centralized consent and opt out process and require that payers notify the attributed physician when their patient opts out of sharing their data via the Provider Access API.

**Payer-to-Payer Data Exchange on FHIR**

CMS is proposing to require impacted payers to implement and maintain a FHIR Payer-to-Payer API to exchange patient claims and encounter data (excluding cost information), data elements identified in the USCDI version 1, and prior authorization requests and decisions when a patient changes health plans. CMS proposes plans must establish and maintain a process for patients to opt into this data exchange via an opt in policy.

The AAFP supports CMS' proposal to require payers to implement and maintain a FHIR based Payer-to-Payer API to exchange patient data when a patient changes plans. Requesting patient data from previous and concurrent payers would eliminate duplicative medical record requests from payers seeking to needlessly have physician offices reapprove medical necessity, retry step therapy requirements, and reauthorize treatments. However, the AAFP believes the Payer-to-Payer API data exchange should be an opt out requirement, like the Provider Access API and Patient Access API, rather than an opt in policy. Under HIPAA, two covered entities could exchange protected health information for treatment, payment, or operations without explicit consent from the patient. It seems reasonable that if a patient had or has a relationship with one payer and now has a relationship with another payer, that a patient would not need to opt in. Therefore, the AAFP believes it is reasonable that a patient should be able to opt out but if a relationship exists, the two payers would be able to exchange patient information for treatment, payment, and operations.

CMS requests comment on whether prior authorizations from a previous payer should be honored by the new payer, and if so, should the honored prior authorizations be limited to a certain period of time based on the type of prior authorization or patient's medical condition.

**The AAFP believes that on receipt of information documenting a prior authorization from the patient or from the patient's health care provider, a payer or utilization review entity should honor a prior authorization granted to a patient from a previous payer or utilization review entity** for at least the initial 60 days of a patient's coverage under a new health plan. Prior authorizations for chronic or long-term care conditions should remain valid for the length of the

treatment. If the patient changes coverage, the prior authorization should remain valid with the new plan. The new plan should not require the patient to obtain a prior authorization again for the health care service.

**Extensions, Exemptions, and Exceptions for Provider Access API and Payer-to-Payer API**

CMS proposes to provide state Medicaid FFS and CHIP FFS programs the opportunity to request a one-time extension of up to one year to implement the Provider Access API, since some states might need to secure funding and staff resources, or a public procurement process to secure contractors, as well as the public health emergency (PHE) unwinding.

CMS proposes to permit state Medicaid FFS and CHIP FFS programs to request an exemption from the Provider Access API requirements when at least 90 percent of their beneficiaries are enrolled in Medicaid or CHIP managed care organizations or entities.

CMS proposes that if an issuer applying for QHP certification to be offered through a FFE believes it cannot satisfy the Provider Access API requirements, the issuer would have to include as part of its QHP application a justification describing the reasons why not, impact, and predicted timeline for compliance.

The AAFP recognizes Medicaid and CHIP agencies may have extenuating circumstances, especially related to the conclusion of the PHE, that may inhibit the timely adoption of these requirements. Along with the proposed flexibilities of extensions, exemptions, and exceptions, we encourage CMS in the final rule to clarify that state Medicaid FFS and CHIP FFS programs, as well as QHPs, must eventually comply with these proposed requirements. Medicaid patients already experience barriers to accessing comprehensive care, including cost and transportation challenges,[xi] bias and discrimination based on their insurance status,[xii] and difficulty scheduling appointments.[xiii] Given these considerations, **the AAFP strongly encourages CMS to work with these payers to help them implement these requirements as soon as feasible, rather than excluding them altogether, to ensure these patients can benefit from these proposed prior authorization reforms to help increase timely access to needed health care services.**

**Improving Prior Authorization Processes**

Proposed Requirement for Payers: Implement an API for Prior Authorization Requirements, Documentation, and Decision (PARDD API). CMS is proposing to require payers to build and maintain a FHIR PARDD API that would automate the process for providers to determine whether a prior authorization is required, identify prior authorization information and documentation requirements, as well as facilitate the exchange of prior authorization requests and decisions from their electronic health records (EHRs) or practice management system.

The AAFP strongly supports this proposal. Determining whether a prior authorization is required and retrieving documentation requirements for each payer imposes a significant administrative burden on our members, as they typically contract with several payers and must navigate across several windows and platforms to obtain this information. This API will instead make these requirements more readily accessible at the point of care, reducing the time required by physicians and their staff to make a prior authorization request. Twenty-eight percent of family physicians participating in a 2022 AAFP survey reported contracting with up to ten payers while 22 percent of family physicians received payments from 14 or more payers.[xiv] Implementing standard APIs could reduce the time

required to manually find and apply these requirements for the numerous plans that physicians contract with, as well as reduce the cost to physician practices.

Once the relevant standards have matured and are widely available, we encourage CMS to expand upon this proposal to require plans to implement an electronic prior authorization program that facilitates real-time prior authorization decisions for items and services that are routinely approved. We note that this program was included in the Improving Seniors' Timely Access to Care Act, a federal bill that passed the House during the 117th Congress and enjoyed strong bipartisan support in Congress, as well as broad support from a range of health care stakeholders. Real-time decisions are needed to truly address the care delays caused by prior authorization.

Requirement for Payers to Provide Status of Prior Authorization and Reason for Denial of Prior Authorizations. CMS is proposing to require impacted payers to include a specific reason when they deny a prior authorization request, regardless of the method used, to facilitate better communication and understanding between the provider and payer and, if necessary, a successful resubmission of the prior authorization request.

The AAFP supports this proposal and recommends CMS implement this policy earlier than 2026. We believe plans are able to use their current method of communication with practices to provide status updates and denial reasons in 2024, and that the final rule should encourage them to do so. According to a recent Kaiser Family Foundation study of prior authorization in MA plans, the vast majority (82 percent) of appeals resulted in fully or partially overturning the initial prior authorization denial.[xv] With more transparency around decision-making for prior authorizations, we hope that the administrative burdens of fulfilling requests and appealing denials on both physicians and health plans will decrease over time.

Requirements for Prior Authorization Decision Timeframes and Communications. CMS is proposing to require MA organizations and applicable integrated plans, Medicaid FFS programs, and CHIP FFS programs to send prior authorization decisions no later than seven calendar days for non-urgent ("standard") requests and no later than 72 hours for urgent ("expedited") requests. CMS seeks comment on alternative time frames with shorter turnaround times.

The AAFP agrees with CMS that it is vital to minimize care delays caused by prior authorizations, and we appreciate the agency's efforts to improve prior authorization response times. Family physicians report significant frustration with payer response time, and we believe outlining required timeframes will be beneficial. However, we remain concerned the proposed required timelines will not meaningfully improve payer response time. **The AAFP recommends non-urgent prior authorizations be fulfilled within 48 hours, while urgent prior authorizations should receive a response within 24 hours.** We continue to believe that these timeframes would lessen care delays and administrative burden while also improving patient experience.

CMS proposes that if a payer fails to meet the timeline for approval or other decision, providers should contact the payer to obtain the status of the request and determine if supporting documentation is needed to complete processing of the authorization or if there are other reasons for the delay in a decision.

**The AAFP strongly recommends against placing the burden of unfulfilled prior authorization requests on the physician and patient instead of the plan that has failed to respond.** This undermines the incentive and proposals in this rule for plans to respond to their own prior authorization requirements within a timely manner.

Public Reporting of Prior Authorization Metrics. CMS is proposing to require impacted payers, on an annual basis, to publicly report aggregated data about the percent of prior authorization requests approved, denied, and approved after appeal, and average time between submission and decision.

The AAFP supports this proposal as greater transparency will be valuable to patients and clinicians as they choose health coverage and the payers with which to contract. We urge CMS to implement this policy earlier than 2026. We believe added transparency regarding the volume of PA requirements and response time could drive process improvement and eventually reduce administrative burden and care delays. The AAFP further recommends CMS expand upon this proposal to require more detailed data reporting on prior authorization requests. For example, prior authorization requirements could be broken down by types of service (radiology, procedural, surgical, lab testing, durable medical equipment, medication, etc.), cost of service, or other criteria. These more detailed reports will help patients and clinicians better understand trends in prior authorization requests and what might be most relevant to their care. Finally, we recommend CMS require impacted payers to also report prior authorization or other requests that are ultimately handled through a "peer-to-peer" consultation between the treating clinician and the plan's medical director or other employed clinician.

CMS is considering including a gold-carding measure as a factor in quality ratings for MA organizations and QHPs as a way for payers to raise their scores in quality star ratings and help alleviate provider burden.

The AAFP is supportive of policies like gold carding that reduce the volume of prior authorizations. However, there are several considerations for implementing these programs to ensure they successfully reduce care delays and administrative burden. The AAFP believes CMS should consider the broad-scope, comprehensive care that family physicians deliver when considering gold carding threshold requirements. Due to the breadth of this care, it may be difficult for family physicians to meet the minimum threshold for orders of each service to qualify for the gold card. Physicians who provide more subspecialized care are more easily able to meet gold carding thresholds. The outcome could be that specialists benefit from gold carding programs while family physicians are excluded due to these requirements. Given that family physicians are more likely to practice in rural and other underserved areas, this would result in access disparities and additional barriers to care for already underserved populations.[xvi]

Primary care physicians manage a wide range of health conditions requiring medications for a broad spectrum of diseases. Most family medicine practices participate with or seven or more insurance companies which necessitates navigating each payer's rules and processes. As we've repeatedly noted, obtaining prior authorizations for medications is time consuming and burdensome for family physicians. The AAFP believes medications should be included in gold carding programs in addition to procedures, testing, and durable medical equipment. Not including drugs in gold carding programs would significantly diminish the positive impact on family physicians and their patients.

**Electronic Prior Authorization Measure for MIPS Eligible Clinicians and Hospitals and Critical Access Hospitals**

CMS is proposing a new measure titled "Electronic Prior Authorization" under both the Health Information Exchange (HIE) objective in the MIPS Promoting Interoperability performance category for MIPS eligible clinicians and the Medicare Promoting Interoperability Program for eligible hospitals and critical access hospitals. To meet the measure, a prior authorization must be requested

electronically from the PARDD API using data from certified EHR technology (CEHRT). Impacted clinicians and hospitals would be required to report the number of prior authorizations for medical items and services (excluding drugs) that are requested electronically from a PARDD API using data from CEHRT.

**The AAFP strongly opposes this proposal and has long opposed the creation of additional process measures under the MIPS Promoting Interoperability category.** Prior authorization is a top administrative burden for physicians. The key purpose of these APIs, particularly the PARDD API, is to provide value to physicians by making patient data more readily available and reducing administrative burden. If these APIs achieve those goals when they are implemented, and electronic prior authorization decreases physician burden, physicians and other clinicians will not need additional incentives to adopt them and they should not be subject to punitive action if they do not implement the requirements in time. There will be wide and rapid adoption as long as their CEHRT provides the functionality. The AAFP encourages CMS to instead focus on ensuring APIs are implemented within physicians' clinical workflow and supported by CEHRT.

**Interoperability Standards for APIs**

CMS proposes modifications to required standards for APIs, permitted upgrades to updated standards, and recommended standards and implementation guides to support APIs.

The AAFP strongly supports standardization of specific FHIR standards and implementation guides across all payers. Variability across payers leads to waste, confusion, delays, and administrative burden. However, we agree with CMS that, because the relevant standards and implementation guides have not fully matured, it would be inadvisable to specify requirements at this time. **The AAFP strongly believes that standards and implementation guides, especially and most importantly, those that are mandated, must first undergo real-world testing to demonstrate that they are adoptable and effective to ensure they are usable in daily practice.** Otherwise, their mandated adoption will not lead to the desired outcomes and may cause harm.

The AAFP notes that this is a reoccurring challenge: agencies often cannot specify required standards or implementation guides at the same time as they are conducting rulemaking because the standards have not yet matured. This leads to a period of time during which vendors, payers, and other stakeholders implement requirements using different standards, leading to confusion, additional burden, and disrupting interoperability. To address this challenge, the AAFP encourages CMS and ONC to implement a maturation process for developing standards, available to the public, so stakeholders can view the specific metrics the standards are meeting and the timeline to required or mandated use. For example, CMS and ONC could share a checklist of testing and other requirements a standard must meet before being required for use under federal regulation. The agency could share where in the process each standard is, signaling to the market how quickly and successfully a standard is advancing through the maturation process and thus, how soon it may be required for use. Transparency in the standards development process will be helpful for stakeholders to adequately prepare for any future updates. The AAFP welcomes the opportunity to work with CMS and ONC to operationalize this recommendation.

**Enforcement**

**We urge CMS, in the final rule, to clearly outline how enforcement of these requirements will be conducted.** While we understand enforcement authority and procedures will differ across impacted payers, clarity on CMS' plans and intention to enforce these requirements is needed to

ensure smooth and timely implementation. The AAFP strongly recommends against relying on physicians or patients to raise complaints about accessing data through APIs, or plan adherence to transparency requirements including status updates and reasons for denials and timeframes for fulfilling prior authorization requests. CMS should outline a process for identifying and addressing noncompliance.

We reiterate that additional requirements and enforcement mechanisms on physicians are not needed to promote the use of relevant APIs. Physicians are overwhelmed by administrative requirements and will utilize technology that relieves burden and promotes efficient workflows. CMS should work with ONC and EHR vendors to ensure that these APIs, once thoroughly tested in real world settings, are widely implemented with EHRs without imposing significant additional cost on physician practices. Removing these barriers to utilization of the APIs will more effectively promote their use among clinicians than penalties, MIPS utilization measures, or other enforcement mechanisms.

**Requests for Information**

Accelerating the Adoption of Standards Related to Social Risk Factor Data. CMS seeks input on barriers the healthcare industry faces to using industry standards and opportunities to accelerate adoption of data collection standards related to social risk factor data, including exchange of information with community-based organizations.

Z codes were developed as a process for physicians and other clinicians to document social needs and social determinants of health (SDOH). However, using Z codes to capture data on social needs is an imperfect solution as these codes are not comprehensive, not paid, and have been under-utilized.[xvii] In instances where Z codes are not paid, there is little incentive to use them, especially if the number of codes on a claim is limited by a physician's EHR or payer. The lack of standardized methodology to collect social needs data creates challenges for health care organizations. For example, if some payers ask for Z codes but other areas use another methodology, such as Logical Observation Identifiers Names and Codes (LOINC), it will simply add burden and confusion on family physicians and other clinicians and will hinder widespread adoption and documentation. We urge CMS to study the challenges to documenting social risk factor data and develop solutions that are consistent and widely adopted by the relevant stakeholders to ensure health care organizations and physician practices can implement solutions efficiently and within existing workflows.

Further, EHRs often aren't yet built to capture social risk factor data, and community-based organizations (CBOs) don't have the funds or technology to capture this information in a way that makes it interoperable. In areas where social risk factor data is collected, many health care organizations may face challenges if their EHR or health information exchange (HIE) cannot efficiently share data between physicians in a patient's care team or across states or regions. Without the functionality to integrate these codes or other documented social risk factor data into patients' complete medical record, patients may be less likely to be connected to resources, other organizations, and services to address any social needs and improve health outcomes in the long-term. We recommend CMS provide funding, resources, and technical assistance to CBOs to enable them to use technology to better integrate social risk factor data into patients' medical records and advance interoperability.

Electronic Exchange of Behavioral Health Information. CMS is seeking feedback on supporting the electronic sharing of behavioral health data between and among behavioral health providers, physicians, other clinicians, and patients.

The AAFP appreciates CMS' commitment to improving care coordination, particularly as it involves behavioral health care. While facilitating data sharing among clinicians and their patients is vital to the advancement of accessible, coordinated behavioral health care, the AAFP notes that there are other challenges in behavioral health care that must be addressed to meaningfully improve access. To begin, the behavioral health workforce shortage has led to increasingly complex primary care visits. Family physicians are well suited to screen and treat certain mental health challenges but are often unable to make referrals when a patient has more complex needs or would benefit from cognitive behavioral therapy or other similar interventions. This is due to not only an overall shortage of mental health professionals but also poor geographic distribution and network adequacy of those clinicians. Without an adequate behavioral health workforce, physicians and patients would be unable to implement or benefit from improved data sharing or innovative care coordination solutions.

Moreover, many family physicians who are able to make referrals to behavioral health professionals find that current EHR systems are incompatible between clinicians in different practices. Integrating behavioral health into primary care increases the likelihood of clinicians having access to an interoperable system, but other barriers like payment and upfront funding continue to limit behavioral health integration. The AAFP continues to advocate for investments in behavioral health integration, improved network adequacy of behavioral health professionals, and parity of payment and non-quantitative treatment limits like prior authorizations or step therapy between medical and mental health benefits. We note that reducing the volume of prior authorization requirements, preventing inappropriate prior authorization denials, and automating prior authorization processes are all essential steps to removing barriers to behavioral health services.

As such, the AAFP strongly encourages CMS to ensure behavioral health treatment data is included in the implementation of the APIs under this proposed rule. As suggested above, the AAFP also strongly encourages CMS to expand this rule to include prescription drugs, including those used for behavioral health treatment.

Improving the Electronic Exchange of Information in Medicare Fee-for-Service. CMS is interested in comments on how Medicare fee-for-service (FFS) might best support improvements to the exchange of medical documentation and health data between and among providers or suppliers. CMS is seeking comment on changes to health IT to account for the need for providers and suppliers to exchange medical documentation, as well as how existing certification criteria can support exchange needs.

The USCDI should continue to expand to account for more structured and semantically defined clinical data. While current efforts on nationwide interoperability should be continued, we see three additional areas that need to be added, starting with certification criteria for write in FHIR APIs for CEHRT. The lack of capability for third parties to write into CEHRT requires the physician to become the data entry clerk or there must be a non-CEHRT workflow added to the physician's current EHR workflow. The second area for certification criteria is around the infrastructure to support third parties to effectively develop, test, and deploy APIs that work with CEHRT. Leading EHRs like athenahealth have such infrastructure, yet most other CEHRT do not, meaning that while a CEHRT is certified to have FHIR APIs, they are not usable in real-world clinical settings. Third, there is a need for a standardized and robust real-world testing infrastructure to ensure real-world testing is done on standards, so that standards can be refined and nationwide outcomes be more predictable. We believe these three additions would allow for more robust and effective interoperability to help the nation achieve the Quadruple Aim.

CMS requests comments on steps the agency can take in health IT and information exchange to assist providers or suppliers in the claim submission process. For family physicians, reducing the number of claims re-submissions and/or improper payments is not primarily a health IT, technology, or process issue. More often, claims re-submissions and improper payments result from convoluted Medicare coverage and payment policies that are often at odds with other payers' requirements. For example, when CMS creates "G" codes that duplicate Current Procedural Terminology (CPT) codes or when CMS defines "prolonged" evaluation and management services differently from CPT, it adds administrative complexity for family physicians attempting to accurately submit a claim. Thus, we urge CMS to simplify coverage and payment policies and align those policies with CPT and other payers to assist family physicians and others in the claim submission process and thereby reduce the number of claims re-submissions and improper payments.

CMS requests comments on any state or federal regulations or payment rules that may be creating barriers to the exchange of information between providers and suppliers, as well as any policies to consider to better facilitate information exchange. Any state or Federal regulation or payment rule that requires the ordering physician to exchange more than one valid order or prescription with the rendering provider/supplier is a barrier to efficient information exchange. The secure exchange of information is best facilitated by eliminating or minimizing the need for multiple exchanges related to a given order/prescription. The operational reality is that family physicians, other primary care physicians, and their practices have no time for the administrivia of multiple exchanges necessitated by Medicare coverage and payment policies. The policies of CMS and its Medicare administrative contractors must be clear and minimal such that the single exchange of a valid order/prescription between the ordering physician and the rendering provider/supplier will suffice.

Finally, the AAFP has long advocated for CMS, ONC, the HHS Office of Civil Rights, and other relevant federal agencies to streamline regulations pertaining to health data privacy and security and health information sharing. We recently submitted comments in support of a proposed rule to align substance use disorder treatment regulations (42 CFR Part 2) with HIPAA. We've also repeatedly emphasized the need to better align HIPAA and information blocking regulations to make compliance less confusing and burdensome for physicians and other clinicians. The AAFP again urges CMS to work with other relevant agencies to clarify how new data sharing requirements interact with these other regulations and provide physicians with clear, specific guidance for how to comply with all relevant regulatory requirements. We urge CMS to clarify in the final rule and subsequent guidance how information blocking and HIPAA regulations apply to data shared through each of these new APIs.

Advancing Interoperability and Improving Prior Authorization Processes for Maternal Health. CMS seeks feedback on how it can leverage information technology to improve maternal health outcomes, including policy approaches to improve interoperability and how prior authorization is used in maternal health care.

The AAFP believes maternity care, including prenatal care, labor and delivery, and postpartum periods, should be exempt from prior authorization requirements. Given the nature of how maternity care is delivered and paid through the global payment system, implementing any prior authorization requirements for these services could result in further care delays that are clinically unacceptable and economically unsustainable for physicians who provide maternity care services. Maternity care is a unique subset of care in which barriers to accessing timely care in any part of pre-pregnancy, pregnancy, or the postpartum period can affect patients' health outcomes in the immediate and long term. The AAFP strongly urges against carving out specific, necessary components of maternity care to be subject to prior authorization requirements.

CMS requests comment on if there are other data elements and classes relevant to care coordination for maternal health that should be added to USCDI. The AAFP supports including the Pregnancy Intention Screening Question (PISQ) as a data element in the USCDI. PISQ is an important component of reproductive health workflows, and its inclusion in USCDI will further support access to person-centered reproductive health care. The AAFP supports pre-pregnancy care as it offers family physicians and their patients an opportunity to discuss any risk factors, minimize them before pregnancy, and work toward improved pregnancy-related and fetal outcomes. Including the PISQ in the USCDI will improve data sharing, care coordination and shared decision making between patients and their primary care physicians.

The AAFP is concerned about the privacy of data for patients seeking reproductive health services, especially following the Supreme Court's ruling on *Dobbs v. Jackson Women's Health*. While clinicians and health care organizations must follow the Health Insurance Portability and Accountability Act (HIPAA)'s Privacy Rule, which protects against disclosures of protected health information (PHI), other entities and data that do not qualify as PHI are not bound by the same rules. This may include third-party health apps that patients may use to access their data via the Patient Access API. Police and prosecutors could potentially obtain extremely detailed information about individuals from technology companies, including internet search histories, communications, finances, and location information and use that information to surveil or charge them for violating state abortion law.

The AAFP's policy on data stewardship, which addresses how de-identified clinical and administrative data derived from physicians' EHRs are collected and used by third parties, states that submission of data from physician practice to third parties must be voluntary, third parties must provide written policies detailing the intended uses of such data, and data storage must adhere to industry and regulatory standards for confidentiality. The AAFP calls on CMS to work with Congress to ensure the security and privacy of patients' health and personal data that exists outside of HIPAA to ensure patients seeking reproductive health services feel safe accessing care and don't feel threatened by fear of criminalization and scrutiny.

Advancing the Trusted Exchange Framework and Common Agreement (TEFCA). CMS seeks comment on how to incentivize payers to enable exchange under TEFCA and concerns stakeholders may have about requirements related to enabling exchange under TEFCA.

TEFCA is an important step in addressing the increasing burdens placed on family physicians and others in the health care system working to deliver continuous, comprehensive, person-centered care in a more integrated fashion. This kind of care requires an efficient and timely exchange of patient information in a standardized and secure manner across multiple organizations. The AAFP supports the goals of TEFCA, is encouraged by the approval of the first set of qualified health information networks (QHINs) and is eager to engage in efforts to ensure its implementation in a manner that meaningfully improves care and health outcomes for patients, while reducing costly and unnecessary administrative burdens placed on physicians and their care teams.

However, we do have concerns about the potential of mandating participation in TEFCA before real-world testing and deployment of QHINs is completed. More real-world information is needed to gauge the impact of TEFCA on achieved interoperability and the burden required to participate. We ask HHS to avoid bypassing the collection of important real-world evidence before moving forward with any required data exchange under TEFCA. Overall, the AAFP looks forward to working with HHS to

improve the exchange of standardized patient health information through TEFCA with evidence-based recommendations.

Thank you for the opportunity to provide comments on the proposed rule. Should you have any questions, please contact Meredith Yinger, Manager, Regulatory Affairs at myinger@aafp.org or (202) 235-5126.

Sincerely,

Sterling N. Ransone, Jr., MD, FAAFP
Board Chair, American Academy of Family Physicians

[i] Armstrong D, Rucker P, Miller M. 2023. UnitedHealthcare Tried to Deny Coverage to a Chronically Ill Patient. He Fought Back, Exposing the Insurer's Inner Workings. *Propublica*. https://www.propublica.org/article/unitedhealth-healthcare-insurance-denial-ulcerative-colitis

[ii] Dickens DS, Pollock BH. Medication prior authorization in pediatric hematology and oncology. Pediatr Blood Cancer. 2017 Jun;64(6). doi: 10.1002/pbc.26339. Epub 2016 Nov 5. PMID: 28436209. https://pubmed.ncbi.nlm.nih.gov/28436209/

[iii] Johnson CY. 2023. I wrote about high-priced drugs for years. Then my toddler needed one. *Washington Post.* https://www.washingtonpost.com/wellness/2023/01/30/high-priced-drugs-step-insurance-policies/

[iv] Liss S. 2022. L.A. Care fined $55M after members faced barriers to timely care. *Healthcare Dive.* https://www.healthcaredive.com/news/la-care-55m-fine-members-barriers-timely-care/619925/#:%7E:text=L.A.%20Care%2C%20the%20nation%27s%20largest,Managed%20Health%20Care%20announced%20Friday.

[v] McManus KA, Powers S, Killelea A, Tello-Trillo S, Rogawski McQuade E. Regional Disparities in Qualified Health Plans' Prior Authorization Requirements for HIV Pre-exposure Prophylaxis in the United States. *JAMA Netw Open.* 2020;3(6):e207445. doi:10.1001/jamanetworkopen.2020.7445

[vi] Identifying How Prior Authorization Impacts Treatment of Underserved and Minority Patients. 2019. Association of Black Cardiologists Access to Care Initiative, Prior Authorization Workgroup. http://abcardio.org/wp-content/uploads/2019/03/AB-20190227-PA-White-Paper-Survey-Results-final.pdf

[vii] Allocation of Physician Time in Ambulatory Practice: A Time and Motion Study in 4 Specialties. 2016. Annals of Internal Medicine.

[viii] Richwine C. 2023. Disparities in Patient Access to Electronic Health Information: Insights from a National Survey. *ONC Health IT Buzz.* https://www.healthit.gov/buzz-blog/health-it/disparities-in-patient-access-to-electronic-health-information-insights-from-a-national-survey

[ix] Improved Diagnostics and Patient Outcomes. 2019. Office of the National Coordinator for Health Information Technology. https://www.healthit.gov/topic/health-it-and-health-information-exchange-basics/improved-diagnostics-patient-outcomes

[x] Most Americans Want to Share and Access More Digital Health Data. 2021. *Pew.* https://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2021/07/most-americans-want-to-share-and-access-more-digital-health-data

[xi] Allen EM, Call KT, Beebe TJ, McAlpine DD, Johnson PJ. Barriers to Care and Health Care Utilization Among the Publicly Insured. Med Care. 2017 Mar;55(3):207-214. doi: 10.1097/MLR.0000000000000644. PMID: 27579910; PMCID: PMC5309146. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5309146/

[xii] Gonzalez D, Kenney GM, O'Brien C, McDaniel M, Karpman M. 2022. Publicly Insured and Uninsured Patients Are More Likely Than Other Patients to be Treated Unfairly in Health Care Settings Because of Their Coverage Type. *Urban Institute.* https://www.urban.org/sites/default/files/2022-09/Publicly%20Insured%20and%20Uninsured%20Patients%20Are%20More%20Likely%20to%20Be%20Treated%20Unfairly%20in%20Health%20Care%20Settings%20Because%20of%20Their%20Coverage%20Type.pdf

[xiii] Hsiang WR, Lukasiewicz A, Gentry M, Kim CY, Leslie MP, Pelker R, Forman HP, Wiznia DH. Medicaid Patients Have Greater Difficulty Scheduling Health Care Appointments Compared With Private Insurance Patients: A Meta-Analysis. Inquiry. 2019 Jan-Dec;56:46958019838118. doi: 10.1177/0046958019838118. PMID: 30947608; PMCID: PMC6452575. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6452575/

[xiv] American Academy of Family Physicians. 2022. Practice Profile Study.

[xv] Biniek JF, Sroczynski N. 2023. Over 35 Million Prior Authorization Requests Were Submitted to Medicare Advantage Plans in 2021. *Kaiser Family Foundation.* https://www.kff.org/medicare/issue-brief/over-35-million-prior-authorization-requests-were-submitted-to-medicare-advantage-plans-in-2021/?utm_source=newsletter&utm_medium=email&utm_campaign=newsletter_axiosvitals&stream=top

[xvi] Primary Care Workforce Facts and Stats No. 3. Agency for Healthcare Research and Quality. US Department of Health and Human Services. Available at: https://www.ahrq.gov/sites/default/files/publications/files/pcwork3.pdf

[xvii] Z Codes Utilization among Medicare Fee-for-Service (FFS) Beneficiaries in 2017. (2020). Centers for Medicare and Medicaid Services. https://www.cms.gov/files/document/cms-omh-january2020-zcode-data-highlightpdf.pdf