AMERICAN COLLEGE of CARDIOLOGY®

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March 13, 2023

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

Comments Submitted Electronically

RE: RIN 0938-AU87 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 Administrator Brooks-LaSure:

The American College of Cardiology (ACC) appreciates the opportunity to provide feedback to CMS on efforts to advance interoperability and improving prior authorization processes for providers and patients participating in the 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 (FFEs). The American College of Cardiology (ACC) is the global leader in transforming cardiovascular care and improving heart health for all. As the preeminent source of professional medical education for the entire cardiovascular care team since 1949, and now with more than 56,000 members from over 140 countries, the ACC credentials cardiovascular professionals who meet stringent qualifications and leads in the formation of health policy, standards, and guidelines. Through its world-renowned family of JACC Journals, NCDR registries, ACC Accreditation Services, global network of Member Sections, CardioSmart patient resources and more, the College is committed to ensuring a world where science, knowledge and innovation optimize patient care and outcomes. Learn more at www.ACC.org or follow @ACCinTouch.

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Introduction

The ACC appreciates the Centers for Medicare & Medicaid Services (CMS) efforts to address the increasingly burdensome prior authorization process. As an original collaborator on the American Medical Association (AMA) Prior Authorization and Utilization Management Reform Principles, the College and its members understand all too well the burdens and inefficiencies associated with the insurance approval process which require dedicated staff, time away from direct patient care on the seemingly endless requests, telephone calls, faxes, denials, and appeals. CMS taking this next step to require important levels of data exchange is vitally important to streamlining the prior authorization process.

The College agrees with the importance of improving the transparency of payer specific prior authorization requirements, streamlining the submission of request and receipt of decisions, and standardizing the length of payer decision-making time. Our members and their staff spend countless hours and resources verifying payer authorization requirements for their patients via web portals and fax machines, calling provider service hotlines as well as completing authorization request forms just in case approval is required.

As the agency is probably aware, each payer has their preferred process—sometimes multiple processes—for submitting prior authorization requests. Decision responses can be approval, denial, request for additional information, or physician to physician discussion. The variability intensifies with contracted third-party prior authorization vendors which have their own web portals and interfaces for information submission and communication. **Standardizing these processes and minimizing variability will improve clinicians' and staff's ability to manage and reduce their work with prior authorizations.** Additionally, establishing a predictable timeline for authorization decisions would provide a level of certainty for clinicians and patients. Due to the high number of prior authorizations needed for patient care, many offices only have time to secure authorization just before the patient visit or appointment for the test or service. If the response is not returned in the established amount of time, the delay will require appointment cancellation, rescheduling, or multiple visits. **Delays in receiving care not only cause rescheduling of appointments and procedures but can impact patient access to necessary medical care. These delays or subsequent denials of essential medical care can lead to patient harm and directly interfere with the clinician patient relationship.** Reducing the burden and complexity of these three issues would provide a more efficient and predictable patient care delivery.

Despite the potential procedural improvements in this proposed rule, the ACC must convey strong concern and opposition to the ever-growing prior authorization requirements for medical procedures, diagnostic tests, and medications across payers. We encourage continued action to fully address the administrative burden of prior authorization, in part by

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being more judicious with deployment of prior authorization. Patients receiving services that are nearly universally approved are unlikely to benefit from prior authorization.
The increased use of prior authorization and the development of associated processes to manage cases is adding to the cost of care for clinicians, their practices, and institutions, decreases the amount of time clinicians spend with patients, and can reduce the quality and timeliness of care patients receive. **In our current health care environment, where decreasing costs and improving quality is a stated aim, it is important that CMS work with patients, payers, and clinicians to reduce the burdens associated with prior authorization, limit the necessity for purchasing expensive health IT systems and capabilities to effectively manage prior authorization caseloads, and focus on improving the quality-of-care patients receive.**

The College understands the need to establish high quality evidence-based cardiovascular care as well as address potential over- and under-utilization of care. The College has a long history of developing practice guideline recommendations, appropriate use criteria and expert consensus documents to educate the medical community on the most effective cardiovascular care. **However, the ACC implores the payer community to create a more selective application of prior authorization and to review existing requirements for elimination.** Regardless of the process improvements, the clinician burdens will only increase as the number of prior authorization requirements continues to increase.

After considering feedback from stakeholders, CMS notes it is withdrawing the December 2020 CMS Interoperability proposed rule and replacing them with updated proposals. The ACC thanks CMS for considering the feedback from stakeholders and making changes to the proposed rule in alignment with these comments. This includes providing stakeholders with additional time to evaluate the proposal and provide substantive comments using a 90-day comment period.

Patient Access API

CMS proposes to add information about prior authorizations to the categories of data required to be made available to patients through the Patient Access API outlined in the CMS Interoperability and Patient Access final rule. **The ACC once again expresses appreciation for CMS' efforts to align technical specifications for prior authorization APIs with those finalized in both the CMS and ONC 21st Century Cures Act final rules.** The proposal to utilize Health Level Seven International® (HL7) Fast Healthcare Interoperability Resources® (FHIR)-based APIs continues the push to use transparent, stakeholder developed, widely available standards. The continued alignment with standards finalized in the 21st Century Cures Act final rules will only help enable adoption by the largest state and national payers. The ACC thanks CMS for working to make information available to patients via APIs. The College has been a constant voice pushing for patients to have expanded access to and use of their health data, including prior authorization decisions, and believes this proposal will help continue this trend.

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In comments submitted to CMS for the December 2020 proposed rule, the College advocated for the expansion of patient access API requirements to include Medicare Advantage plans and the inclusion of any prescription drug and/or covered outpatient drug information. **The ACC thanks CMS for responding to comments requesting the inclusion of Medicare Advantage as regulated payers that must make prior authorization information available via APIs. By doing so, CMS ensures some of the largest payers at the state and national level implement changes to streamline the prior authorization process, adopt a standards-based process, and serve as the driving force for providers' involvement.**

The ACC believes it is equally important that CMS include prescription drug and/or covered outpatient drug information in any information sharing requirements and once again requests that CMS reconsider excluding drugs from prior authorization information sharing requirements and process improvements. Prescription drug and outpatient drug information access will help to preserve the continuity of care for new patients. Medications are an ever-growing part of disease management and patients should have access to such information. Patients now have access to other drug information under the CMS and ONC 21st Century Cures Act final rules and it would only help to promote information sharing and patient empowerment by providing them access to any prior authorization information and decisions regarding their prescription drug and outpatient drug information.

In the December 2020 proposed rule, CMS proposed including a provision that would have required impacted payers request a privacy policy attestation from third party application developers when they approve requests to connect to a payer's Patient Access API. While the College understood the reasoning behind the proposal and desire to protect patients from predatory third-party applications, the ACC expressed concerns for the proposal and requested additional information to better understand the process. After receiving comments, CMS is withdrawing this proposal and will not require privacy policy attestation. The ACC thanks CMS for responding to comments submitted by stakeholders and encourages CMS to work closely with other regulatory agencies, including the Federal Trade Commission which has jurisdiction over applications that fall outside of HIPAA protections, to ensure patients information is protected and third-party applications continue to honor their responsibilities to patients. The ACC also notes it is supportive of comprehensive privacy reform to better protect patient information outside of HIPAA protections. While the College understands this is outside of the scope of these comments and HHS is limited in its ability to expand protections without Congressional action, the College continues to encourage all regulatory agencies to explore methods of protecting patient information and access to their health information.

Under the Patient Access API proposal, impacted payers would be required to make information about prior authorization requests and decisions (and related administrative and

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clinical documentation) for items and services (excluding drugs) available to patients no later than 1 business day after the payer receives the prior authorization request or there is another type of status change for the prior authorization. **The College thanks CMS for proposing to make this information available to patients in an expedient fashion. The ACC also thanks CMS for proposing to require impacted payers to share the same information about prior authorization requests and decisions with a patient's provider via the Provider Access API and via the Payer-to-Payer API Payer to Payer Data Exchange on FHIR.** The alignment of Patient, Provider, and Payer-to-Payer API requirements will help facilitate electronic information exchange and promote much needed transparency and data liquidity into the prior authorization process. **Once again, however, the College reiterates that CMS should expand proposed information requirements to include prescription drug and/or covered outpatient drug information in any information sharing requirements**.

In the proposed rule, CMS states that a potential benefit of these APIs is patients can better understand the timeline and process for prior authorization and plan accordingly. While this is true in theory, context and additional information about the prior authorization process is essential to helping patients understand. **The ACC encourages CMS to require payers to develop educational resources directed towards patients, aligning with a proposal to require payers to develop non-technical and easy-to-understand educational resources for providers under the Provider Access API proposal.** The development of these non-technical materials, combined with the utilization of API access, will promote transparency, and help to ensure patients, providers, and payers are better aligned to reduce the burdens of prior authorization, and ensure patients receive timely access to care they need.

In the proposed rule, CMS requests comment on whether CMS should explore requirements or ways to encourage exchange under TEFCA to ensure that more patients are informed about the privacy and security implications of using health apps to access their health information, consistent with the requirements for Individual Access Services (IAS) Providers described previously. The ACC believes this is a novel approach to ensuring patients are aware of privacy and security implications, but notes that not all health applications will go through the TEFCA process to become IAS providers. Once again, absent much needed comprehensive privacy reform from the Congress, the ACC encourages CMS to work with the FTC and other regulatory agencies to align incentives and enforce regulation of applications that fall outside of HIPAA regulation and explore ways to incentivize third-party applications to utilize best practices, such as those developed by the CARIN Alliance.

Finally, CMS proposes to require impacted payers to report metrics in the form of aggregated, de-identified data to CMS on an annual basis about how patients use the Patient Access API. However, CMS does not plan to publicly report these metrics at the state, plan, or issuer level, but may reference or publish aggregated and de-identified data that does not include names of

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specific state agencies, plans, or issuers. **The ACC encourages CMS to reconsider this proposal and publicly report these metrics.** By making these metrics public, CMS can help patients and stakeholders better understand the impact of access APIs and help inform future innovations that promote patient access and future decision making. **The College also encourages CMS to explore publishing additional information that helps to better understand patient access by historically underserved populations and identify disparities in patient access to health data.** ONC recently published information showing growing disparities in patient access to their health information via health portals and applications and should use this as a model to show how policies impact different populations and inform future decision making. CMS should provide additional transparency to the prior authorization and patient access processes by making as much of this data public as possible while still working to maintain the privacy of patients.

Provider Access API

In the rule, CMS proposes to require that impacted payers implement and maintain a FHIR API that makes patient data available to providers who have a contractual relationship with the payer and a treatment relationship with the patient. The Provider Access API and the Patient Access API would facilitate the FHIR-based exchange of claims and encounter data, as well as all data classes and data elements such as Immunizations, Procedures, and Assessment and Plan of Treatment. Both the Patient Access and Provider Access APIs would require payers to share information related to prior authorization requests and decisions (including related administrative and clinical documentation) for items and services. **The ACC thanks CMS for proposing impacted payers implement a standards-based Provider Access API that makes patient data available to providers both on an individual patient basis and for one or more patients at once using a bulk specification, as permitted by applicable law, so that providers could use data on their patients for such purposes as facilitating treatment and ensuring their patients receive better, more coordinated care.** The College believes this standards-based approach will not only help increase adoption through alignment with other electronic health information sharing requirements implemented in the 21st Century Cures Act final rules, but it also has the potential to reduce the burdens associated with prior authorization by laying the groundwork for future automated processes.

The ACC once again thanks CMS for listening to stakeholder comments submitted in response to the December 2020 proposed rule and expanding Provider Access APIs to include Medicare Advantage. **However, we once again reiterate the need to expanding Provider Access APIs to include prescription drug and/or covered outpatient drug information.** Prescription drug and outpatient drug information access will help to preserve the continuity of care for new patients. Medications are an ever-growing part of disease management and patients should have access to such information. In the rule, CMS states how important APIs are to information sharing, stating APIs "[ensure] that providers have access to relevant patient data at the point of care

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could also reduce the burden on patients to recall and relay information during an appointment and/or provide confirmation that the patient's recollection of prior care is accurate." This is especially important when it comes to drug information and the management of patients with drug prescriptions. The College applauds the work CMS, ONC and other agencies have undertaken to expand access to important clinical information and improve interoperability and encourages continued work to ensure all patient information is eventually made available via standardized APIs to patients, providers, and payers. Doing so can help to prevent duplicative testing, improve patient care, and increase patient participation in their care, all of which are goals everyone in the healthcare system should strive to achieve.

For the Provider Access API, the provider would request and receive access to the patient's information through their Electronic Health Record (EHR), practice management system, or other technology solution for treatment purposes, including care coordination. **It is essential that the implementation of prior authorization interfaces that are incorporated into a providers EHR, practice management system or other technology solution take place in a measured and thoughtful manner, considering provider workflow.** In previous comments regarding the ONC Certified Electronic Health Record Technology (CEHRT) Certification Program, the College has stated the importance of testing workflows and thoughtful implementation of required capabilities into systems through heuristic testing and other methods. **The College once again asks CMS to work with ONC to implement additional requirements as part of the CEHRT certification requirement process to require developers to work with payers to implement prior authorization interfaces that are incorporated into workflow and do not add to EHR complexity. This includes Provider Access APIs.** Without a requirement to include prior authorization systems into EHR workflow, the College is concerned any efforts to help reduce burdens and automate prior authorization processes will be negated.

CMS proposes that beginning January 1, 2026, impacted payers would maintain a process to associate patients with their in-network or enrolled providers to enable payer to provider data exchange via the Provider Access API. As previously stated, the ACC asks that CMS work with ONC to ensure that both payers and CEHRT vendors are aligned in the technical capabilities to implement Provider Access APIs in a way that does not hamper workflow and negate efforts to reduce burdens placed on providers by prior authorization.

In the proposed rule, if a provider does not have a provider agreement or is not enrolled (in the case of Medicaid and CHIP FFS programs) with a payer that holds their patient's data, the payer would not be required to provide patient data to that provider under this proposal, though it may be permissible or even required by other law or regulation. **The College opposes this proposal and encourages CMS to follow the proposal in the December 2020 regulation which stated payers cannot deny use of or access to the Provider Access API based on whether the provider using the API is under contract with the payer.** The December 2020 proposal aligned

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with Congress', CMS' and ONC's intent to end information blocking once and for all and the College is disappointed CMS is not continuing its march towards free-flowing information sharing between patients, providers, and payers regardless of contractual status or enrollment. Historically the use of contracts as blockades to information exchange has stifled interoperability and been a source of information blocking. **The College strongly recommends CMS reconsider this proposal and require payers who have the technical ability must respond to provider information requests via API to help promote essential information exchange and allow patients and providers to have access to important health information contained in prior authorization processes.**

CMS proposes that all impacted payers would be required to establish and maintain a process to allow patients or their personal representatives to opt out of having the patients' data available for providers to access through the Provider Access API. **The College thanks CMS for listening to comments submitted in response to the December 2020 proposed rule and changing the proposal from an opt-in to an opt-out process.** As CMS notes, an opt-out model encourages the utilization and usefulness of data sharing efforts between patients and healthcare provider and the ACC agrees a proposal defaulting to share data with providers, unless a patient opts out, appropriately balances the benefits of data sharing with the right of patients to control their health information.

Payer to Payer Data Exchange on FHIR

CMS proposes to require impacted payers (MA organizations, state Medicaid FFS programs, state CHIP FFS programs, Medicaid managed care plans, CHIP managed care entities, and QHP issuers on the FFEs) to implement and maintain a payer-to-payer data exchange using a FHIR-based API. CMS also proposes to rescind the payer-to-payer data exchange policy previously finalized in the CMS Interoperability and Patient Access rule to prevent industry from developing multiple systems, and to help payers avoid the costs of developing non-standardized, non-API systems, and instead builds on the technical standards, base content and vocabulary standards used for the Patient Access API for the proposed Payer-to-Payer API. **The ACC supports these proposals and thanks CMS for its efforts to continue to build on FHIR-based information exchange. This payer-to-payer data exchange and updated standards for the CMS Interoperability and Patient Access Final Rule, coupled with Payer Access and Provider Access APIs, builds upon the efforts of ONC and CMS to facilitate interoperability and will help to ensure correct information is available to patients, providers, and payers when they need it rather than waiting for analog information exchange that can take weeks and lead directly to patient harm.**

CMS proposes to establish a patient opt in policy for payer-to-payer data exchange for all impacted payers rather than an opt-out policy, such as is proposed for the Provider Access API. **The ACC encourages CMS to establish an opt-out policy for payer-to-payer data exchange due**

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to the stated benefits such policies have on increasing data exchange. As CMS notes in its own comments in the Provider Access API proposal, opt in models of data sharing has been shown to inhibit the utilization and usefulness of data sharing efforts. The College is concerned patients will not easily be able to opt-in to information sharing, leading to disparities in access to prior authorization information for patients and providers when a patient changes their insurer. Opt-out policies can encourage information sharing while still protecting patient choice and privacy, as shown in the Provider Access API proposal. If legal barriers prevent the creation of an opt-out policy for payer-to-payer data exchange, the ACC encourages CMS to explore methods to require payers to include language allowing for opt-in consent in an easy to find way such as a requirement for payers to provide patients with easy to understand consent during the enrollment process or, as CMS discusses, the ability for patients to easily opt-in to data exchange between payers through required patient education resources that provide information on the benefits of API-based data exchange and specific and easy to follow instructions and access to technical support to encourage beneficiary opt-in.

CMS proposes that impacted payers would be required to make information about prior authorizations available via the Payer-to-Payer API for the duration that the authorization is active and, for at least 1 year after the prior authorization's last status change. **The College seeks clarification from CMS on how this proposal would align with the requirement that impacted payers make available any of the applicable patient data with a date of service on or after January 1, 2016, in the Provider Access API proposal.** The ACC could envision disparities in data access for historical prior authorization requests that could be lost in payer-to-payer data exchange but required for providers to have access to under the Provider Access API proposal.

In the recently proposed *Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications* rule, CMS proposes regulations to require Medicare Advantage Organizations to implement a 90-day transition period for previously approved prior authorizations to ensure the continuity of patient care when enrolling into a new Medicare Advantage payer. It is well known that patient care is often disrupted during enrollment changes between payers and will likely cause the prior authorization process to start all over again. Simply changing Medicare Advantage plans should not halt previously payer approved treatment plans. **The College implores CMS to establish this proposed type of continuity of care transition period for other payers in addition to Medicare Advantage.**

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Requesting Data Exchange from a Patient's Previous and/or Concurrent Payer(s) and Responding to such a Request

CMS proposes to require impacted payers, within 1 week of the start of a patient's coverage, to exchange data with any concurrent payers that the patient reports. The proposal also states that should an impacted payer receive a request for a current patient's data from a known concurrent payer for that patient, the receiving payer must respond with the appropriate data within 1 business day of receiving the request. **The ACC thanks CMS for supporting the timeliness of information exchange between payers to ensure prior authorization and other care decisions are made in a timely manner.**

Payer to Payer Data Exchange in Medicaid and CHIP

CMS proposes to make the proposed payer to payer data exchange applicable to state Medicaid and CHIP FFS programs. CMS believes proposing to require Medicaid and CHIP FFS programs to implement the Payer-to-Payer API data exchange policies in this proposed rule would not be as burdensome as proposing to require them to follow the non-API-based payer to payer data exchange policies that were finalized in the CMS Interoperability and Patient Access final rule. **The ACC thanks CMS for continuing to implement rules that facilitate information exchange and improve interoperability.** As CMS states, ensuring that patient data can follow Medicaid and CHIP beneficiaries as they enter these programs, potentially leading to better care coordination and continuity of care for these patients while also reducing burdens placed on patients and providers.

Improving Prior Authorization Processes

Once again, the College thanks CMS for listening to stakeholder feedback on the December 2020 CMS Interoperability proposed rule and expanding the scope of this proposed rule to include the Medicare Advantage program. By doing so, CMS is working to ensure some of the largest payers at the state and national level implement changes to streamline the prior authorization process, adopt a standards-based process, and serve as the driving force for providers' involvement.

In the December 2020 CMS Interoperability proposed rule, CMS proposed two separate APIs the Document Requirement Lookup Service (DRLS) API and the Prior Authorization Support (PAS) API. CMS proposes functionally combining these two APIs into a new FHIR-based API, the Prior Authorization Requirements, Documentation, and Decision (PARDD) API. In comments submitted to CMS in 2020, the ACC supported the development of the APIs, but cautioned against the premature requirement of standards use by providers before the standards were fully developed, widely available, and mature. In the years since, CMS has continued to work with HL7, payers, providers, and developers to continue development of these APIs to ensure the standards utilized for the PARDD API are ready for widespread utilization. **Coupled with a 2026 implementation date, the ACC thanks CMS for working to give payers, developers, and**

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providers sufficient time to prepare for widespread utilization of these APIs and building on policies implemented through the Cures Act final rules. The College believes that wide adoption of the proposed PARDD API will provide much needed transparency for clinicians and their staffs to maneuver through the multitude of payer requirements.

While supportive of the PARDD API, the ACC does ask for clarification from CMS and additional education and technical assistance for providers on how the PARDD API will work in tandem with proposals in the *Administrative Simplification: Adoption of Standards for Health Care Attachments Transactions and Electronic Signatures, and Modification to Referral Certification and Authorization Transaction Standard* proposed rule. In this proposed rule, HHS proposes to adopt a modification to the standard for the referral certification and authorization transaction (X12 278) to move from Version 5010 to Version 6020 for "health care attachments" transactions, including prior authorization transactions. The Advancing Interoperability and Improving Prior Authorization Processes proposed rule requires impacted payers to implement an HL7 FHIR API that would work in combination with the adopted HIPAA transaction standard (currently v 5010 but proposed to shift to v 6020) to conduct the prior authorization process. This means that under the multiple and concurrent rulemaking processes, organizations would need to utilize three standards for prior authorization with documents and signatures: FHIR, X12 278, and the CDA. The College is concerned the adoption of concurrent new standards may lead to implementation challenges and undue burdens and costs for providers. It will be necessary for organizations to subscribe to or purchase additional software capabilities to handle electronic prior authorization requests. The ACC requests CMS provide additional details on how the proposed PARDD API and updated X12 standards may work in tandem without needlessly complicating implementation and execution by payers, developers, and providers.

In the proposed rule, CMS recommends the use of certain HL7 FHIR Da Vinci Implementation guides that have been developed specifically to support the functionality of the PARDD API**. The ACC thanks CMS for thoughtfully working with HL7 and others to develop policies and implementation guides that align with one another.** By doing so, CMS works to ensure providers can use CEHRT that has built in capabilities developed to ensure compliance with new prior authorization regulations and seamless information transfer between payers, patients, and providers.

<u>Requirement for Payers to Provide Status of Prior Authorization and Reason for Denial of Prior Authorizations</u>

The ACC thanks CMS for proposing payers provide a specific reason for denied prior authorization decisions, regardless of the method used to send the prior authorization request. Currently, practices will often receive denial notices for missing information or stating that medical necessity has not been met. However, these reasons are not actionable for the

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requesting clinician because they do not provide specific information on the requirements that have not been met.

In the December 2020 CMS Interoperability proposed rule, CMS sought comment on prohibiting post-service claim denials for items and services approved under prior authorization. However, CMS did not seek additional comment nor propose any policies impacting the use of this tactic by payers in the updated proposed rule. **The College once again reiterates support for prohibiting the post-service claim denials for services and tests approved under prior authorization and encourages CMS to implement policies that work to streamline the prior authorization process, improve efficiencies, and reduce needless delays to patient care.** Too often the work associated with obtaining a prior authorization approval is nullified with post-service claim denial. To obtain a prior authorization approval, the requesting clinician can be required to provide the patient's clinical conditions, treatment preferences, previous diagnostic and lab test results, care management plans and professional rationale. After providing this information and receiving approval, a payer should not be allowed to render the authorization moot.

<u>Requirements for Prior Authorization Decision Timeframes and Communications</u>
In comments submitted to CMS for the December 2020 CMS Interoperability proposed rule, the ACC stated it considers no later than 72 hours for expedited reviews and no later than 7 calendar days for standard reviews to be reasonable timelines for prior authorization decision making. **The College thanks CMS for listening to stakeholder input and proposing to reduce the time require for notice of prior authorization decisions.** However, in the proposed rule, CMS offers a different timeline for QHPs on the FFEs, which would be required to provide notification of a plan's benefit determination within 15 days for standard authorization decisions and within 72 hours for expedited requests. **The ACC encourages CMS to work to align prior authorization notification requirements across all impacted payers.** Discrepancies in notification requirements will confuse patients and providers, as they may not know whether a patient is covered by a QHP on the FFE.

While the ACC is encouraged by the progress CMS is making to help expedite prior authorization review and notifications, the ACC strongly encourages CMS to promote more efficient and timely options including removal of prior authorization, real-time approvals, and retroactive prior authorization submissions. Cardiology outpatient office visits are often for patients being assessed for their current or recent symptoms such as chest pain, palpations and shortness of breath which would necessitate diagnostic cardiac testing or direct the patient to the newest. Some patients would be considered urgent, but not emergent cases. Many of these patients must arrange different transportation methods and must travel great distances. In the best case, the patients would be evaluated and provided the diagnostic test on the same day during the same visit. However, several cardiac testing modalities administered in the

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outpatient setting like stress echocardiograms and nuclear cardiac stress testing require prior authorization from numerous payers. If this proposed rule is implemented, a lack of real-time decisions will require the cardiologists and patients to choose whether to wait the 72 hours for an expedited review and schedule a second visit or direct the patient to the nearest emergency room, resulting in higher costs and patient dissatisfaction. Real-time decisions are made across the country every day and some payers with real-time automated approvals allow for such immediate testing and care planning. In these urgent cases, providing greater clinician flexibility and adhering to patient preference will reduce the potential for care delays.

Public Reporting of Prior Authorization Metrics

CMS proposes to require impacted payers to publicly report certain aggregated metrics about prior authorization by posting them directly on the payer's website or via a publicly accessible hyperlink(s). The ACC believes it would be helpful for impacted payers to report on the impact prior authorization has on the quality-of-care patients receive, potential delays in care, and associated cost savings due to the prior authorization process. Public reporting of this data can help policy makers, researchers, providers, and patients all make more informed decisions about the prior authorization process, ensuring that patient care remains central.

The ACC thanks CMS for promoting transparency through the public reporting of aggregated metrics but encourages CMS to require this information to be machine-readable and easily findable on payer websites. Stakeholders and federal agencies can learn from the implementation of the new price transparency rules, where pricing information is often difficult to find or inaccessible to most individuals without advanced programs to decode and sort the information. Instead, CMS should work to make the public reporting process as easy as possible to encourage stakeholders, researchers, and other interested parties to view and learn from publicly reported prior authorization metrics.

"Gold-Carding" Programs for Prior Authorization

Addressing the administrative burdens cardiovascular clinicians face on a day-to-day basis is a key priority for the ACC, and oversight of prior authorization practices is consistently rated as a top policy priority among our members. Prior authorization, a cost-control tool utilized by health plans, can result in distraction and delays to patient care and generate unnecessary paperwork.

Recent (AMA) survey data show that 93 percent of physicians report care delays or disruptions associated with prior authorization. AMA data also show that 34 percent of physicians report that prior authorization has led to a serious adverse event (e.g., hospitalization, permanent impairment, or even death) for a patient in their care and that 91 percent of physicians see prior authorization as having a negative effect on their patients' clinical outcomes. Moreover, the Office of Inspector General (OIG) 2022 report found that 13 percent of prior authorization

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requests denied by Medicare Advantage (MA) plans met Medicare coverage rules, and 18 percent of payment request denials met Medicare and MA billing rules. The ACC supports the goals the AMA developed for refined prior authorization and management reform principles centered around clinical validity, continuity of care, transparency and fairness, timely access and administrative efficiency, and alternatives and exemptions.

In the proposed rule, CMS seeks comment for consideration for future rulemaking on how to measure whether and how such gold-carding or prior authorization exemption programs could reduce provider and payer burden and improve services to patients. **The ACC thanks CMS for seeking stakeholder input on methods to reduce provider burdens in respect to prior authorization and improve services to patients.**

In respect to gold-carding program implementation, the ACC supports several key provisions outlined in the Getting Over Lengthy Delays in Care as Required by Doctors (GOLD CARD) Act, introduced in 2022 by Reps. Michael Burgess, MD and Vincente Gonzalez which would exempt qualifying providers from prior authorization requirements under MA. The legislation has received support from other medical specialty groups and organizations. The ACC supports language in the legislation that "**a physician shall be exempt from the prior authorization requirements under such process for the period of such plan year with respect to a specific item, service, or group of similar services, if during the preceding plan year at least 90 percent of prior authorization requests submitted to such organization by such physician for such item, service, or group were approved by such organization (including any approval granted after an appeal).**" The ACC urges any policies to include language that an **MA organization may not evaluate a physician for the exemption more than once during any plan year,** to prevent additional administrative burdens for clinicians.

The ACC believes that the 90 percent threshold required for an exemption must also include approvals granted after appeal. When determining whether a physician qualifies for exemption, the MA organization shall **"treat any claim that was initially denied, subsequently appealed, and that remains pending appeal at the time of such calculation as having been approved if more than 30 days have elapsed since the date of such appeal was filed."**

The ACC recommends that if a physician's gold card is under review by the MA organization, the physician under review should receive a peer-to-peer review. The MA reviewer should **possess a current and nonrestricted license to practice medicine in the State in which such item or service is to be furnished; be actively engaged in the practice of medicine in the same or similar specialty as the physician being reviewed; knowledgeable about the furnishing of, and has experience furnishing, such an item or service.** It is essential that any gold card program allow enrolled clinicians to be exempt from prior authorization requirements to sufficiently outweigh any application and reapplication time requirements to the program. If a clinician was

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required to reapply in short intervals, it may negate the time and efficiency savings seen on prior authorization paperwork.

The ACC thanks the agency for listening to stakeholder concerns regarding burdensome prior authorization practices. We urge CMS to implement policies to reduce the prior authorization burden for clinicians and ensure that patients have timely access to medically necessary care. While gold card programs do not eliminate the challenges of prior authorization, the College believes it will provide some necessary relief and demonstrate how providers, patients, and health plans can work together to improve care while reducing costs.

Electronic Prior Authorization for the Merit-based Incentive Payment System (MIPS) Promoting Interoperability Performance Category and the Medicare Promoting Interoperability Program

CMS proposes a new measure for the MIPS Promoting Interoperability performance category for MIPS eligible clinicians and the Medicare Promoting Interoperability (PI) Program for eligible hospitals and critical access hospitals (CAHs) that would require healthcare providers to request a prior authorization electronically using data from CEHRT using a payer's PARDD API. The new measure will be included in the Health Information Exchange (HIE) objective for the PI performance category and will measure the number of unique prior authorizations requested electronically from a PARDD API using data from CEHRT. CMS proposes a MIPS eligible clinician, eligible hospital, or CAH that fails to report the measure or claim an exclusion would not satisfy the MIPS Promoting Interoperability performance category or Medicare Promoting Interoperability Program reporting requirements.

The ACC has supported CMS efforts to promote the adoption of CEHRT and encourage participation in new initiatives, such as efforts to promote the use of TEFCA through alternative measures under the HIE objective. However, the College has several concerns regarding the proposed Electronic Prior Authorization measure. Over the last few years, CMS has made concerted efforts to reduce MIPS reporting burdens and focus on developing meaningful measures. Many of the new, meaningful measures that have been introduced are optional and purposefully designed to incentivize adherence to newly implemented regulations. The College is concerned by making the new Prior Authorization measure an all or nothing required measure, CMS is backtracking on progress made to reduce the number and burden of measures eligible clinicians, eligible hospitals, or CAHs must report. While the proposed measure would not be scored during the first year, CY 2026**, the ACC encourages CMS to make this new measure optional for eligible clinicians, eligible hospitals, and CAHs.**

The College is also concerned that by making the new prior authorization measure required, CMS is forcing practices and institutions to take on additional costs related to the purchase, installation, and maintenance of software that meets the PARDD API requirements. It is naïve to

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think CEHRT vendors will simply install electronic prior authorization software that meets new requirements without additional costs on providers and hospitals. Often, these costs outweigh the monetary benefits associated with the creation of new measures, such as the proposed prior authorization measure**. To avoid CMS giving providers an unfunded mandate and monetary burden that will outweigh benefits afforded by successfully meeting MIPS requirements, the ACC requests CMS make this new measure optional for eligible clinicians, eligible hospitals, and CAHs until a time where the benefit, both monetarily and in reduced administrative burdens, can be quantified for a calculated return on investment.**

The College is also concerned about the criteria CMS proposes for the numerator for the new measure. Under the proposal, only prior authorizations that are requested electronically from a PARDD API using data from CEHRT would be included in the numerator. Prior authorization requests that are made using fax, mail, or portal would be included in the denominator of the measure unless the prior authorization cannot be requested using the PARDD API because the payer does not offer an API that meets the PARDD API requirements, in which case it would be excluded from the denominator.

As currently proposed, this measure would capture the use of APIs for prior authorization for a different patient population than other MIPS measures, making it difficult to perform an apples-to-apples comparison of the benefits for Medicare populations. Current MIPS measures are designed to capture information on Medicare populations and the proposed prior authorization regulations are not directed towards Medicare as a payor. While there would be some overlap of patients such as dual-eligible patients, the ACC believes the patient population this measure would apply to would largely different than the population MIPS measures are designed to measure. **The College is also concerned documentation for requests that meet the numerator criteria could be difficult for eligible clinicians to document and track, making proper reporting of the measure burdensome and time consuming.** Staff would be forced to spend countless hours reconciling and documenting every prior authorization request over the year to properly account for the filing process and reporting it for measure consideration. While the College believes the PARDD API can help to reduce the burdens of prior authorization requests, most payers will still utilize other methods for prior authorization requests, requiring the development of bifurcated processes to document and record adherence for measure reporting under the MIPS program. The College requests CMS reconsider the proposed numerator and denominator for the Prior Authorization measure and utilize an attestation process for the measure.

<u>Request for Information: Advancing the Trusted Exchange Framework and Common Agreement (TEFCA)</u>

The ACC is supportive of efforts by CMS and ONC to promote the use of TEFCA as a facilitator for improved interoperability and standardized electronic information exchange. It is important

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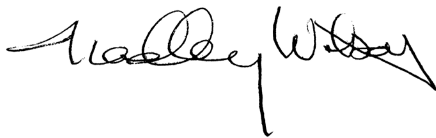
that any future requirements of the Common Agreement and the Qualified Health Information Network (QHIN) Technical Framework (QTF) not only align with the finalized Cures Act regulations but are widely implementable in a standardized fashion. The ACC recognizes that TEFCA is one tool CMS and ONC can use to help facilitate improved information exchange and is not going to deliver semantic interoperability by itself. TEFCA is still a voluntary agreement, and while there are incentives in place to encourage participation, many actors throughout the healthcare system will not participate in TEFCA for some time. CMS should ensure that any requirements placed on payers, providers, and other actors recognize that there will still be diverse methods for information exchange that do not align with TEFCA requirements and accordingly safeguard against punitive measures against these actors until standards and implementation reach a mature and steady state.

Conclusion

The ACC appreciates the opportunity to provide input to CMS as it considers ways to advance interoperability and improving prior authorization processes for providers and patients participating in the 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. If you have any questions or follow up, please contact Joseph Cody, Associate Director of Health IT and Digital Heath Policy at jcody@acc.org or (202) 375-6251.

Sincerely,



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