AMERICAN COLLEGE of CARDIOLOGY

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January 4, 2021

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-9123-P
P.O. Box 8016
Baltimore, MD 21244-8016.

Comments Submitted Electronically

Dear Administrator Verma,

The American College of Cardiology (ACC) appreciates the opportunity to comment on the proposed *Medicaid Program; Patient Protection and Affordable Care Act; Reducing Provider and Patient Burden by Improving Prior Authorization Processes, and Promoting Patients' Electronic Access to Health Information for Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, and Issuers of Qualified Health Plans on the Federally-facilitated Exchanges; Health Information Technology Standards and Implementation Specifications* regulations.
The ACC envisions a world where innovation and knowledge optimize cardiovascular care and outcomes. As the professional home for the entire cardiovascular care team, the mission of the College and its more than 54,000 members is to transform cardiovascular care and to improve heart health. The ACC bestows credentials upon cardiovascular professionals who meet stringent qualifications and leads in the formation of health policy, standards, and guidelines. The College also provides professional medical education, disseminates cardiovascular research through its world-renowned JACC journals, operates national registries to measure and improve care, and offers cardiovascular accreditation to hospitals and institutions.

Introduction

The ACC greatly appreciates the Centers for Medicare & Medicaid Services (CMS) working 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 referenced in the proposed rule, 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 requirements, streamlining the submission of request and receipt of decisions, and standardizing the length of payer decision-making time. Our members and staff spend countless hours and resources verifying payer authorization requirements for their patients via web portals, calling provider service hotlines as well as completing authorization request forms just in case approval is required.

As you are 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 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 pure 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 being more judicious with deployment of prior authorization. Patients receiving services that are nearly universally approved are unlikely to benefit from prior authorization. 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 prior authorization requirements continues to increase.

Proposed Rule Comment Period

In addition to CMS' work to address burdens associated with the prior authorization process, the College appreciates CMS' effort to align technical specifications for prior authorization application programing interfaces (APIs) with those finalized in the *21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program* and *Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-facilitated Exchanges, and Health Care Providers* rules. **However, the proposed comment period is insufficient for stakeholders to consider the implications of this rule and provide substantive comments to CMS.** The ONC and CMS 21st Century Cures Act proposed rules had 90-day comments and almost an entire year between proposed and final rule publication. This afforded stakeholders ample time to review, understand, and prepare for the rules. CMS released the public inspection copy of the proposed prior authorization rule on December 10, 2020 and set a deadline for comments on January 4, 2021. Federal offices are closed December 24, 25, and January 1, leaving stakeholders only 13 business days to evaluate the rule, understand the proposals, determine the scope and impact of the proposed regulations, and draft comments. **Due to this unprecedented short comment period, the ACC recommends CMS provide stakeholders additional time to evaluate and provide comments and extend the comment period by an additional 60 days.** As CMS states in the rule, burdens associated with prior authorization are among the most pressing issues and a main contributor to physician burnout. It is important that stakeholders are provided an appropriate amount of time to submit thoughtful comments on this proposal. Several proposals upon which the ACC comments briefly below would have been considered more thoroughly were a traditional comment period followed.

Patient Access API

The ACC once again expresses appreciation for CMS' efforts to align technical specifications for prior authorization APIs with those finalized in 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.

CMS proposes that information about prior authorization decisions be made available to patients through the patient access APIs in addition to the accessible content finalized in the CMS Interoperability and Patient Access final rule. 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 ownership of their health data, including prior authorization decisions, and**

any relevant health and administrative information should be included in any data accessible to patients.

The College believes CMS should address several gaps in the proposed rule in any future rulemaking, including 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 inclusion of Medicare Advantage payers in any patient access API is necessary to ensure 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. It is equally important that CMS include prescription drug/ and or covered outpatient drug information in any information sharing requirements.** 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 proposed rule, CMS intends to require impacted payers request a privacy policy attestation from third party app developers when their app requests to connect to the payer's Patient Access API. **While the ACC appreciates this effort to protect patient information, especially in the context of third-party applications that fall outside the scope of Health Insurance Portability and Accountability Act (HIPAA) protections, the ACC requests additional details and a clearer understanding of attestation and privacy requirements for the implementation of this process.** While the College is understanding of CMS' desire to abstain for regulating attestation processes with too heavy a hand, the ACC is concerned a lack of specificity and uniformity in the regulations that are being rushed could lead to a wide range of policies that make it confusing for patients and undermine trust in the system.

Finally, the ACC encourages CMS to work with ONC to implement additional standards as part of the Certified Electronic Health Record Technology (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 patient 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 for naught.

Provider Access APIs

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.

However, we reiterate the proposed rule has several gaps that the College believes CMS should address in any future rulemaking, such as expanding provider access API requirements to include Medicare Advantage plans and including any prescription drug/ and or covered outpatient drug information. **The inclusion of Medicare Advantage payers in any provider access API is necessary to ensure 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. It is equally important that CMS include prescription drug/ and or covered outpatient drug information in any information sharing requirements.** 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. The College once again asks CMS to work with ONC to implement additional standards 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.

The ACC thanks CMS for proposing 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. This proposal aligns with Congress', CMS' and ONC's intent to end information blocking once and for all. Historically the use of contracts as blockades to information exchange has stiffed interoperability and these proposals will help promote essential information exchange and allow patients and providers to have access to important health information contained in prior authorization processes.

CMS proposes impacted payers would be permitted to put a process in place for patients to opt-in to use of the provider access API for data sharing between their payer and their providers. While the College understands the intent behind this proposal, the ACC is concerned providers may not know which patients have opted into the use of provider access APIs. This issue would be especially complicated and pronounced with dual-eligible patients where certain information could be unnecessarily segmented from providers depending on which payer covers a service. The College encourages CMS to more thoughtfully consider ways to allow patients to control access to their data while still allowing providers to access important health information necessary for continuity of care and treatment.

Importance of Engaging the Provider Community

CMS must ensure local payers with significant market share participate and share prior authorization data in order for the provider community to widely adopt the use of the proposed APIs. Although this proposal is limited to the impacted payers, providers will need the large national and state commercial payers to publicly state their intention to roll-out a similar program for their members. In addition to the plans, EHR vendors will likely be the driving force for providers' involvement. While many of these EHR vendors will be capable of incorporating these API standards and frameworks into existing EHRs, **the College is greatly concerned about significant upgrade and implementation costs and resources for clinician practices and health systems.**

As mentioned in this proposed rule, State Medicaid agencies may have access to matching federal funds to cover a portion of their upgrade and implementation costs; the provider community will need similar support for needed equipment, training, IT contractors and EHR upgrade costs. Finally, providers, especially solo, small, and medium-sized practices will need low-cost participation options from their EHR vendors and possibly the payers. **The College is concerned with implementation costs for practices as they work through and attempt to recover from the uncertainty of the National Public Health Emergency.**

Proposed Requirement for Payers: Documentation Requirement Lookup Service (DRLS) API

It is the College's understanding that most payers are obligated to provide advanced notification (60 or 90 days) through provider newsletters (mailed and/or electronic) and the provider section of payers' websites and provider web-portals. Clinicians and administrative staff regularly review the various newsletters and communications for new or changing prior authorization programs. At times, new requirements for a service or medication are only first discovered after a denial claim or rejected pharmacy fill, often leaving no option of appeal.

It is important to highlight that payer requirements not only vary, but a payer's various coverage plans also differ. This adds to provider confusion. Additionally, access to requirements is by third-party prior authorization vendors contracted by the payers. Often, payer websites will direct providers to the vendors for the specific rules. **The College believes that wide adoption of this proposed DRLS would provide much needed transparency for clinicians and their staffs to maneuver through the multitude of payer requirements.**

Proposed Requirement for Payers: Implementation of a Prior Authorization Support API

The ACC supports the proposal that impacted payers implement a Prior Authorization Support (PAS) API that facilitates a prior authorization request and response. We understand that the prior authorization environment is currently so varied that significant standardization is vitally important. At the same time, we do not want to see technological improvements such as automated decision-making

lost in the process. User interfaces that support real-time decisions and minimal human interaction should be encouraged while understanding that not all prior authorization programs can achieve it. CMS notes that functionality to interact with the proposed prior authorization support API is not standardized across provider systems today, but that industry interest in this initiative is extremely high. While the ACC appreciates efforts from both public and private stakeholders to develop these support APIs, **the ACC cautions against the premature requirement of standards use by providers before such standards are developed, widely available, and mature.** The creation of FHIR-based standards is a transparent process with wide-spread industry buy-in and the ACC trusts the development process underway. However, until these support APIs are incorporated into a vast majority of EHR systems, providers should not be required to utilize any prior authorization support APIs.

Requirement to Provide a Reason for Denial

While the ACC supports the concept of requiring impacted payers to send certain response information regarding the reason for denying a prior authorization request, CMS should require the reason for denial to be more specific than proposed. 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 requesting clinician. The College would like payers to be as specific as possible with their denial reasons and provide references to the missing information and coverage policy, practice guidelines, or appropriate use criteria.

Prohibiting Post-Service Claim Denials for Items and Services Approved Under Prior Authorization

The College supports prohibiting the post-service claim denials for services and tests approved under prior authorization. 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.

Requirements for Prior Authorization Decision Timeframes and Communications

The College appreciates CMS standardizing prior authorization decision timeframes and communication rules. While some states and localities have mandated processing requirements**, it is vitally important for providers to learn when their authorization request will be completed and communicated back to them. We consider no later than 72 hours for expedited reviews and no later than 7 calendar days for standard ones to be reasonable.** The reduction from 14 to 7 calendar days for Medicaid managed care and CHIP managed care payers would be greatly appreciated. The ACC understands that these timeframe rules are intended to set a maximum, yet we encourage CMS and the impacted payers to strive for real-time automated decision-making.

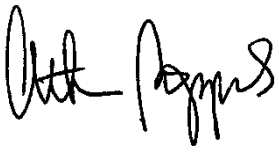
Expedited Reviews

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. 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 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. 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. **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.**

Conclusion

The ACC appreciates CMS' consideration of the comments provided in response to the proposed *Medicaid Program; Patient Protection and Affordable Care Act; Reducing Provider and Patient Burden by Improving Prior Authorization Processes, and Promoting Patients' Electronic Access to Health Information for Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, and Issuers of Qualified Health Plans on the Federally-facilitated Exchanges; Health Information Technology Standards and Implementation Specifications* regulations. Should you require additional information regarding the College's comments on the ACC's prior authorization reform efforts in further detail, please contact Henry McCants, Payer Relations Associate, at hmccants@acc.org or (202) 375-6642. For additional information regarding the ACC's API comments, please contact Joseph Cody, Associate Director, Research and Innovation Policy, at jcody@acc.org or (202) 375-6251.

Thank you,



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