

March 13, 2023

Officers

Sunil V. Rao, MD, FSCAI

President

George D. Dangas, MD, MSCAI

President-Elect

Timothy D. Henry, MD, MSCAI

Immediate Past President

James B. Hermiller, MD, MSCAI

Vice President

Srihari S. Naidu, MD, FSCAI

Secretary

Arnold Seto, MD, MPA, FSCAI

Treasurer

Trustees

Mirvat Alasnag, MD, FSCAI

Joaquin E. Cigarroa, MD, MSCAI

Ramesh Daggubati, MD, FSCAI

Thomas E. Fagan, MD, MSCAI

Daniel M. Kolansky, MD, FSCAI

Alexandra J. Lansky, MD, FSCAI

Binita Shah, MD, FSCAI

Rajesh V. Swaminathan, MD, FSCAI

Molly Szerlip, MD, FSCAI

Trustees for Life

Submitted electronically via: <http://www.regulations.gov>

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-0057-P
P.O. Box 8016
Baltimore, MD 21244-8016

RE: 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

Dear Administrator Brooks-LaSure,

The Society for Cardiovascular Angiography and Interventions (SCAI) has dedicated its work to advancing the profession and is the primary society for guidance, representation, professional recognition, education, and research opportunities for invasive and interventional cardiology professionals. For more than 40 years, SCAI has personified professional excellence and innovation globally, fostering a trusted community of more than 5000 members dedicated to medical advancement and lifesaving care for adults and children with cardiovascular disease.

SCAI appreciates the opportunity to comment on this proposed rule. SCAI supports the regulatory changes set forth in this proposed rule. These regulations will reduce barriers to care and lessen burden associated with current prior authorization requirements. SCAI would like to echo many of the comments being made by the Regulatory Relief Coalition in response to this proposed rule.

While implementation of the reforms described in this proposed rule will significantly expedite the prior authorization process, this proposed rule, unlike the prior authorization proposed rule for Medicare Advantage, does not ensure that prior authorization criteria are supported by clinical evidence. SCAI urges CMS to include in the final rule parallel requirements intended to assure that the criteria of all payers are supported by clinical literature, that they are made public in advance of adoption; and that they are reviewed by physicians with expertise in the services involved prior to implementation.

The proposed rule would require payers to implement and maintain an Application Program Interface (“API”) to support and streamline the PA process; respond to prior authorization requests within certain timeframes; provide a clear reason for prior authorization denials; and publicly report on prior authorization approvals, denials, and appeals. SCAI strongly supports these proposals. However, SCAI is concerned that that the preamble to the proposed rule solicits input on whether, and to what extent, the approach to prior authorization reflected in the rule may be applicable under Medicare fee for service (FFS). SCAI opposes use of prior authorization under Medicare FFS and urges CMS to suspend any existing FFS prior authorization policies that are not mandated by legislation. We believe that expanding prior authorization in Medicare FFS has the potential to significantly limit Medicare patients’ access to medically necessary care and should not be adopted.

API Creation

SCAI supports CMS’ proposal to require payers to make available a Provider Access API. We believe that the availability of this API has the potential to improve care coordination and minimize unnecessary duplication of services. The inclusion of information regarding which prior authorization requests have been submitted and approved will significantly reduce delays in the provision of medically necessary care and relieve provider burden. However, SCAI 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.

The proposed rule does not require any of the three APIs to include information regarding prior authorization requests and decisions for drugs. It is important for patients to have access to this information to facilitate patient-provider joint decision making and for providers to have this information to ensure that patients receive medication that is medically appropriate. For these reasons, SCAI believes that the prior authorization request and decision history for all drugs be included in all three APIs.

The proposed rule requires that payers make claims and encounter data available within one business day of this request. To ensure that this requirement does not result in inappropriate pressure on providers to submit claims immediately after the provision of an item or service, we request that this requirement be clarified such that it applies only to the claims and encounter information available at the time of the request.

Decision Timeframes

To address prior authorization decision timeframes, CMS proposes that impacted payers must provide notice of prior authorization decisions as expeditiously as a beneficiary's health condition requires but no later than seven calendar days for standard requests and no later than 72 hours for expedited requests. SCAI urges CMS to modify the timeframe for organization determinations to reflect the deadlines that are set forth in the Improving Seniors' Timely Access to Care Act (S. 3018/H.R. 3173) (the "Improving Seniors' Access bill" or "the Bill"), which was unanimously passed by the House of Representatives by voice vote in September 2022. Specifically, while both the Bill and the proposed rule require decisions within 7 days of a request, the proposed rule allows 72 hours for an expedited request while the Bill would require a decision within 24 hours. We believe that, for cases designated as the treating physician as urgent, a delay of up to three days has significant potential to jeopardize patient health and safety. SCAI urges CMS to require non-urgent prior authorizations be fulfilled within 7 days while urgent prior authorizations should receive a response within 24 hours.

SCAI also believes that CMS should consider other steps that it might take to encourage payers to implement real-time prior authorization decisions for services that are frequently approved, as described in the Bill. Implementation of such a program has the potential to virtually eliminate the delay associated with many prior authorization requirements and facilitate seamless patient care.

Regardless of which deadlines are adopted, SCAI is extremely concerned that the proposed rule does not include a workable enforcement mechanism to ensure that the deadlines are met. The preamble to the rule indicates that if a payer fails to comply with a deadline, it is up to the provider to follow up with the payer or, alternatively appeal the failure to comply with the deadline. SCAI believes that unless failure to comply with a deadline is deemed to constitute an approval of the prior authorization request, payers have little incentive to treat deadlines seriously. SCAI 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. We urge CMS to allow providers to treat a failure to respond in a timely fashion as a

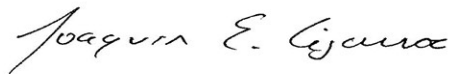
prior authorization approval, thereby incentivizing payers to comply with requests as required by regulation.

SCAI appreciates the opportunity to provide comments on this Proposed Rule and we look forward to continuing working with CMS to address these important issues. If SCAI can be of any assistance as CMS continues to consider and review these issues, please do not hesitate to contact SCAI's manager, coding and reimbursement Monica Wright at 202-327-5451 or at mlwright@scai.org if there are any questions or further requests.

Sincerely,

A handwritten signature in black ink that reads "Lyndon C. Box". The signature is written in a cursive style with a large, stylized initial 'L'.

Lyndon Box, MD, FSCAI
Chair
Government Relations Committee

A handwritten signature in black ink that reads "Joaquin E. Cigarroa". The signature is written in a cursive style with a large, stylized initial 'J'.

Joaquin Cigarroa, MD, MSCAI
Co-Chair
Government Relations Committee