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January 4, 2021

Administrator Seema Verma
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3401-IFC
P.O. Box 8016
Baltimore, MD 21244-8016

Don Rucker, M.D.
Office of the National Coordinator for Health Information Technology
Department of Health and Human Services
330 C Street SW
Floor 7
Washington, DC 20201

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

Re: 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 [CMS-9123-P]

Dear Administrator Verma and Dr. Rucker:

On behalf of the American Urological Association (AUA), thank you for the opportunity to provide comments on CMS-9123-P proposed rule regarding reducing provider and patient burden by improving prior authorization processes. The AUA is a globally engaged organization representing the world's largest collection of expertise and insight into the treatment of urologic disease. Of the total AUA membership, more than 15,000 are based in the United States and provide invaluable support to the urologic community by fostering the highest standards of urologic care through education, research and the formulation of health policy. Prior authorization process improvement is among AUA's highest priorities, given the burdens prior authorization imposes on providers and the negative health consequences it can cause for patients. The AUA thanks the Centers for Medicare & Medicaid Services (CMS) and the Office of the National Coordinator for Health Information Technology (ONC) for addressing these pressing issues and working to improve patient care.

Current State of Prior Authorization in Urology

Prior authorization requirements continue to delay patient access to clinically appropriate care and therapies. Guidelines from insurers are not always consistent with specialty guidelines, and prior authorization requirements and coverage denials frequently supersede clinician judgement, creating obstacles to patient care. Prior authorization requirements should support clinically effective treatments and encourage safe prescription practices. AUA members also incur significant costs to compensate the office staff necessary to complete prior authorization requirements. Electronic health records (EHRs) can and should be optimized to improve these processes and better support provider efficiency and the delivery of high-quality patient care.

These challenges are particularly acute for outpatient drugs. AUA members frequently experience challenges with health plan drug formularies, which designate the drugs a health plan will cover. Frequent formulary changes force physicians to modify patients' prescriptions over time to minimize patients' out-of-pocket costs. The lack of the formulary integration in EHRs can result in coverage denials and delayed patient care. Without electronic integration of drug formularies in an EHR, physicians may not have the information necessary to prescribe the medication that is both appropriate for the patient and covered by the patient's insurance. There is an urgent need to improve this process and support better integration of patient-centered formularies into EHRs, which should be optimized to provide physicians with up to date and accurate formulary information.

72 Hour Response Time

The AUA supports CMS and ONC's proposal to require that CHIP and state Medicaid programs communicate expedited requests for prior authorization as expeditiously as the beneficiary's health condition requires, but no later than 72 hours after receiving a request for an expedited determination. The AUA requests clarification on whether the 72 hours proposed in the rule includes weekends and holidays – e.g., must an expedited determination requested at noon on Friday be returned by noon on Monday or noon on Wednesday. To minimize delay in needed urological care, the AUA recommends that the 72 hour requirement be interpreted to include weekends and holidays. The AUA also encourages CMS and ONC to extend this requirement to Medicare fee for service, Medicare Advantage, and private health plans to the extent possible under existing regulatory authority.

Health Plan Type

The AUA encourages CMS and ONC to implement standards that are consistent across all plan types, including Medicare Advantage plans and qualified health plans on insurance exchanges, to the extent permitted by its existing regulatory authority. Inconsistent requirements across payers, whether in prior authorization or otherwise, create confusion and burden for providers who must navigate the various requirements. Additionally,

inconsistent requirements across plans also require providers to purchase technology that can maintain multiple standards simultaneously.

Repeated Prior Authorization Requests

The AUA thanks CMS and ONC for the solicitation of comments on repeat prior authorizations for chronic conditions. AUA members treat many patients with chronic or life-long conditions that require life-long treatment, such as Botox for patients with neurogenic bladder or catheters for paraplegic patients. Repeated approval processes, which health plans nearly always grant after physicians submit the required paperwork, adds an extra, unnecessary step that frequently delays patients' access to necessary treatments. Prior authorization application programming interfaces and processes should include opportunities to designate chronic or life-long conditions for which the treating physician does not anticipate recovery or improved condition so that these requests do not need monthly or annual renewal. Such an option would minimize both payer and provider burden and lessen the likelihood that patients with chronic and life-long conditions will receive delayed care.

CMS and ONC should also consider policy solutions to address prior authorization requirements with high rates of approval. AUA members report that, for certain services or drugs, prior authorization requests are nearly always approved. While AUA understands that prior authorization is one method for health plans to control health care expenditures, the burden of prior authorization should not be used to dissuade physicians from recommending, or patients from accessing, medically appropriate drugs or services. CMS and ONC should use data from electronic prior authorization processes to identify drugs and services for which prior authorization is most frequently approved, with an aim towards eliminating prior authorization requirements for drugs and services for which prior authorization has minimal utilization management benefit.

Services, Equipment, and Outpatient Pharmaceuticals

In the proposed rule, ONC and CMS requested comment for consideration on whether payers should be required to include information about prescription drug and/or covered outpatient drug pending and active prior authorization decisions as the proposed rule would require of other items or services. The AUA believes that such a proposal would be beneficial to both patients and physicians. As described above, prior authorization for drugs is the primary source of prior authorization burden for our members and their patients. While some payers have made progress with making patient formularies accessible via electronic health record, not all EHR vendors integrate this information. A mandate from CMS or ONC to make this information available and integrate the information into existing workflows would encourage health plans and EHR vendors to collaborate to make this information available.

These requirements should apply to both health plans and pharmacy benefit managers as both frequently change their formularies, requiring physicians to change their prescribing

to ensure that their patients have access to affordable drugs. Any future rulemaking should require health plans and PBMs to make this information available to EHR vendors in a timely manner, and both health plans and EHRs should alert physicians and other prescribing providers when formulary changes occur so that they can respond accordingly. While electronic notification of prior authorization criteria is important for equipment and services, prior authorization criteria for medications and formulary changes occur much more frequently because they are typically driven less by medical necessity than by rebates available to PBMs. For that reason, the AUA urges CMS and ONC to undertake rulemaking to facilitate more effective and patient-friendly rules on health plan prior authorization requirements and processes – for services, equipment, and outpatient drugs.

Reducing the Use of Fax Machines

The AUA welcomes the opportunity to provide guiding information on CMS' ongoing effort to facilitate effective, secure, and efficient use of emerging data exchange technology for the purpose of timelier and more coordinated care. Fax machines have played an integral part in health care data sharing for decades, but as the rule notes, the lack of simple integration into a patient's EHR limits the future viability of the technology in an interoperable eco-system.

The volume of medical records being sent by fax machine for review continues to decrease each year among urologist. Typically, only small urological practices in rural areas send records primarily by fax machine. These providers may have challenges in the use of newer technology if fax machines were eliminated entirely. Those challenges may include bandwidth limitations due to locality and coverage, and delays in personnel training and competency when changing to an entirely new technology and process.

Solutions for practices with these challenges could include a delayed phase-out of fax machine technology over a set period to allow training and competency with a new system to occur. Fax machines could play a role for several years as a back-up system for select areas in the event of internet data service loss or degradation below the threshold needed to send information. The current federal definition of fixed terrestrial broadband by the Federal Communications Commission (FCC) is 25 megabits per second (Mbps) download speed, 3 Mbps upload speed; speeds the FCC estimates 77.7% of rural areas within the US can achieve.[1] Under the same FCC estimate, 99.4% of rural areas are covered under mobile LTE speeds of 5 Mbps download, 1 Mbps upload, a far more encompassing metric. CMS should consider the FCC broadband definition as a ceiling for bandwidth needs when planning system interoperability and integration.

[1] *Deployment (Millions) of Fixed Terrestrial 25/3 Mbps; Mobile LTE With a Minimum Advertised Speed of 5/1 Mbps; and Mobile LTE With a Median Speed of 10/3 Mbps by State, District of Columbia, and U.S. Territory (As of December 31, 2018)*, Federal Communications Commission. https://docs.fcc.gov/public/attachments/FCC-20-50A2.pdf

American Urological Association

Thank you again for the opportunity to comment on these important issues. Please do not hesitate to contact Raymond Wezik, Director of Policy and Advocacy if the AUA can be of any further assistance.

Sincerely,

Eugene Rhee, MD, MBA
Chair, Public Policy Council