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March 25, 2022

**ELECTRONIC SUBMISSION**

Micky Tripathi, Ph.D., M.P.P.
National Coordinator for Health Information Technology
U.S. Department of Health and Human Services (HHS)
Office of the National Coordinator for Health Information Technology
Mary E. Switzer Building
Mail Stop: 7033A
330 C Street SW
Washington, DC 20201

**RE: Request for Information: Electronic Prior Authorization Standards, Implementation Specifications, and Certification Criteria**

Dear Dr. Tripathi,

On behalf of the Advanced Medical Technology Association (AdvaMed), we appreciate the opportunity to provide information to HHS on electronic prior authorization standards, implementation specifications, and certification criteria. AdvaMed member companies produce the medical devices, diagnostic products, and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. AdvaMed members range from the largest to the smallest medical technology innovators and companies. We are committed to ensuring patient access to lifesaving and life-enhancing devices and other advanced medical technologies in the most appropriate settings.

We ask that the Office of the National Coordinator (ONC) for Health Information Technology provide consideration for ensuring that third parties such as medical device manufacturers can access prior authorization web portals for the purpose of assisting patients and providers with health insurance prior authorization requests. We strongly believe that enabling medical device manufacturers to help patients and providers navigate through the prior authorization process in the most efficient, effective, and transparent manner possible is key to achieving the common

objectives of timely patient access to medically necessary therapies and the alleviation of administrative burden for providers.

While most prior authorization requests are submitted by physicians' offices and medical facilities, some health care providers may utilize third parties, such as medical device manufacturers, for prior authorization support services. Manufacturers and providers have standard processes in place to collect the required information in a HIPAA compliant manner in order to assist patients in accessing the treatment recommended by their physicians, while reducing the inefficient use of provider and staff time. The AdvaMed Code of Ethics on Interactions with U.S. Health Care Professionals states the following:

> *Permissible activities involving the provision of coverage, reimbursement, and health economic information may include…Facilitating patient access to the Company's Medical Technologies by providing Health Care Professionals with assistance in obtaining patient coverage decisions from payors, including providing information on payor policies and training on procedures for obtaining prior authorization, providing sample letters and information on medical necessity and appeals of denied claims.*
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> *In addition, at the request of a Health Care Professional to facilitate patient access to the Company's Medical Technology, and subject to appropriate privacy safeguards, the Company may assist the patient by facilitating the preparation and submission of requests for coverage determinations, prior authorizations, pre-certifications and appeals of denied claims, relating to a Company's own Medical Technology; however, such assistance should not be provided as an unlawful inducement.*[1]

Medical device manufacturers offering prior authorization support services are dedicated to providing transparency regarding their role in the submission process when interacting with a beneficiary's payer. This transparency ensures that there is no confusion surrounding the entity supporting the submission request. However, the current design of prior authorization web portals requires users to register under a physician or facility Tax ID and National Provider Identifier (NPI). This registration requirement does not allow third parties to register on the portals and forces prior authorization support service staff to continue using outdated and inefficient methods of relaying information to the payers, such as faxing and phone calls. In this way, the omission of third-party prior authorization support services from electronic processes slows requests and leads to delays in appropriate patient care, which could be avoided if web portals were viable for third party use.

We recognize that as new, innovative medical devices continue to be developed, prior authorization support services will be needed to assist providers who seek to

[1] AdvaMed Code of Ethics on Interactions with U.S. Health Care Professionals. Available at https://www.advamed.org/wp-content/uploads/2021/05/AdvaMed-Code-of-Ethics-2021.pdf.

use these devices to meet their patients' medical needs. Medical device manufacturers, physicians, and other healthcare providers share a common goal of providing patient access to the best possible treatments without inappropriate delays, and we applaud HHS for expressing a strong commitment to reducing barriers to patient access and alleviating administrative burden where possible.

We respectfully request that HHS provide a mechanism for medical device manufacturers to utilize web portals to submit prior authorization requests directly on behalf of our patients and providers. We believe this access could be made possible through a software update allowing medical device prior authorization support services employees to register using an identifier other than an NPI. Allowing access in this way ensures that support services can work quickly and effectively for patient access while providing the necessary transparency surrounding the prior authorization request.

As the ONC works within HHS to consider methods to streamline and reduce burden associated with electronic prior authorization, we urge the Department to consider broader policy challenges associated with the use of prior authorization programs. First, these programs can impose unreasonable timelines on administrative tasks, leading to delayed access to needed services and creating health risks for patients awaiting critical care. In addition, a recent American Medical Association survey found 88 percent of provider respondents believe prior authorization processes generate "high or extremely high burden", and more than 8 in 10 providers indicated prior authorization issues sometimes, often, or always led to patients abandoning their treatment.[2] Concepts such as "gold carding" programs[3] may be one approach to recognizing and reducing burden on high-performing clinicians who consistently request authorization for appropriate services. Finally, and most importantly, some studies suggest prior authorization processes further compound the unique challenges faced by underserved and minority patients accessing healthcare, and in turn affect their health outcomes.[4] In consideration of the above, we urge HHS to continue efforts to address physician burden and remove barriers to patient access of timely, appropriate care.

We appreciate this opportunity to share our recommendations for your consideration regarding electronic prior authorization standards, implementation specifications, and certification criteria. If you have any questions, please contact Kirsten Tullia (ktullia@advamed.org).

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[2] https://www.ama-assn.org/system/files/prior-authorization-survey.pdf
[3] See e.g., TX H.B. 3459. Reg. Sess. 2021-2022 (2021). Relating to preauthorization requirements for certain healthcare services and utilization review for certain health benefits plans. Available at: https://legiscan.com/TX/bill/HB3459/2021**.**
[4] See e.g., The ABC Access to Care Initiative, Identifying How Prior Authorization Impacts Treatment of Underserved and Minority Patients. (2019). Available at: http://abcardio.org/wp-content/uploads/2019/03/AB-20190227-PA-White-Paper-Survey-Results-final.pdf**.**

Sincerely,

Chandra N. Branham, J.D.

Senior Vice President and Head of Payment & Healthcare Delivery Policy