December 23, 2020

Alex Azar, Secretary
Department of Health and Human Services
200 Independence Avenue SW, Room 713F
Washington, District of Columbia 20201

Submitted electronically via regulations.gov

Re: Regulatory Relief to Support Economic Recovery; Request for Information (RFI)

Dear Secretary Azar,

The American Academy of Dermatology Association (AADA) represents close to 14,000 dermatologists nationwide. We are writing to provide comments on the US Department of Health and Human Services' (HHS) *Request for Information on Regulatory Relief to Support Economic Recovery* (85 Fed. Reg. 75720 (November 25, 2020). The AADA is committed to excellence in the medical and surgical treatment of skin disease; advocating for high standards in clinical practice, education, and research in dermatology and dermatopathology; and driving continuous improvement in patient care and outcomes while reducing the burden of disease. Dermatologists diagnose and treat more than 3,000 diseases, including skin cancer, psoriasis, immunologic diseases, and many genetic disorders. One in four Americans suffers or will suffer from a skin disease. As dermatologists are at the forefront of the fight against skin cancer and treating numerous skin diseases, the Academy appreciates HHS' commitment to providing regulatory relief to support economic recovery from the COVID-19 public health emergency (PHE).

This request for information (RFI) seeks feedback on whether the many rules that were issued during the public health emergency should be extended. We recognize the Secretary's desire for swift rulemaking to address one of the leading administrative challenges facing provider organizations, clinicians, and patients and for soliciting input from the industry on the topics included in the RFI. However, due to the complexity, breadth and importance of these regulations we strongly urge you to extend the public comment period a minimum of 30 days. We appreciate the opportunity to provide

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feedback and urge HHS to take our brief recommendations and initial concerns into consideration when formulating future policy.

Relaxation of HIPAA Requirements for Telehealth Remote Communications

Early in the pandemic, HHS instructed the Office of Civil Rights (OCR) to use its discretion to not impose penalties for HIPAA violations against healthcare providers in connection with their good faith provision of telehealth using remote communication technologies during the COVID-19 nationwide public health emergency. It is important that patient access to care – when provided by telemedicine – is of high quality, contributes to care coordination, meets state licensure and other legal requirements, maintains patient choice and transparency, and protects patient privacy. That being said, the delivery of video telemedicine across all platforms during the PHE has been beneficial to facilitate patients' access to care. It has demonstrated that patients are comfortable using platforms for live interactive telemedicine that they are familiar with, although some of those platforms might not be HIPAA compliant. We encourage HHS and the Office of the National Coordinator for Health Information Technology (ONC) to study how to bridge this gap so that after the PHE, patients will be able to use live interactive telemedicine platforms in a manner that is both of high quality and protects patient privacy.

Originating Site Requirement for Telehealth

Sec. 1834(m) of the Social Security Act requires that several conditions must be met for Medicare to make payments for telehealth services under the Medicare Physician Fee Schedule. The service must be on the list of Medicare telehealth services and meet all of the following additional requirements:

- The service must be furnished via an interactive telecommunications system.
- The service must be furnished by a physician or other authorized practitioner.
- The service must be furnished to an eligible telehealth individual.
- The individual receiving the service must be located in a telehealth originating site.

When all of these conditions are met, Medicare pays a facility fee to the originating site and makes a separate payment to the distant site practitioner furnishing the service. The originating site must be in an area that is designated as a rural health professional shortage area or in a county that is not included in a Metropolitan Statistical Area or from an entity that participates in a Federal telemedicine demonstration project that has been approved by (or receives funding from) the Secretary of Health and Human Services.

The HHS Secretary used waiver authority under the PHE to loosen the requirements during the pandemic. Although the AADA recognizes that any changes to the originating site requirement will

require an act of Congress, we do recommend and support a full study of the impact this waiver has had on all underserved and marginalized populations.

Lengthier Virtual Check-ins

The Centers for Medicare and Medicaid Services (CMS) is not able to waive the requirement that telehealth services be furnished using an interactive telecommunications system that includes two-way, audio/video communication technology. However, the need for audio only interaction could remain beyond the PHE as beneficiaries desire to avoid sources of potential infection, such as a doctor's office; and in that circumstance, a longer phone conversation may be needed than what is described by the virtual check-in. The AADA strongly recommends that CMS should develop coding and payment for a service similar to the virtual check-in but for a longer unit of time and with an accordingly higher value. There are occasions when a longer virtual check-in may be needed. The AADA supports development of coding and payment for this service. We recommend that the coding be developed through the CPT process and that the RUC develop valuation recommendations.

Direct Supervision by Interactive Telecommunications Technology

During the PHE, CMS adopted a policy revising the definition of direct supervision to include virtual presence of the supervising physician or practitioner using interactive audio/video real-time communications technology. The AADA supports this extension on a temporary basis through the end of the PHE, to ensure the safety of clinicians and patients. This policy is appropriate to mitigate infection exposure risk to patients and clinicians. When the PHE ends, the exposure risk will as well. Therefore, we recommend CMS return to requiring in-person direct level supervision after the PHE to ensure appropriate care.

Scope of Practice Expansion

During the PHE, CMS has allowed nurse practitioners (NPs), clinical nurse specialists (CNSs), physician assistants (PAs) and certified nurse-midwives (CNMs) to supervise the performance of diagnostic tests as a substitute for to physicians. There are currently Medicare regulations that contain more stringent supervision requirements than existing state scope of practice laws, or that place guardrails on health professionals to prevent clinicians from practicing beyond the scope of their license. We agree that state law should prevail in determining scope of practice. That said, the AADA supports a physician led health care team to assure optimum care. With seven or more years of postgraduate education and more than 10,000 hours of clinical experience, physicians are uniquely qualified to lead health care teams. By contrast, nurse practitioners (NPs) must complete only two to three years of graduate level education and 500-720 hours of clinical training. Physician assistant (PA) programs are 26 months in length and require 2,000 hours of clinical care. NPs and PAs are

integral members of the care team, but the skills and acumen obtained by physicians throughout their extensive education and training make them uniquely qualified to oversee and supervise patient care. Physician-led team-based care has a proven track record of success in improving the quality of patient care, reducing costs, and allowing all health care professionals to spend more time with their patients. In the absence of state law that defines these supervision requirements, we strongly urge pulling back the expansion of scope that was relaxed during the pandemic. At a minimum, CMS should reinstate the requirement that these diagnostic tests must be supervised by physicians.

Ease Prior Authorization

CMS issued waivers encouraging Medicare Advantage Organizations and state Medicaid programs to waive or relax plan prior authorization requirements during the PHE. This was done to facilitate access to services with less burden on beneficiaries, plans, and providers. CMS Administrator Seema Verma has stated that, "Prior-authorization requirements are a primary driver of physician burnout … and, even more importantly, patients are experiencing needless delays in care that are negatively impacting the quality of care." We appreciate CMS recognizing that when processes are not in place to quickly review and approve requests for treatments, tests, services and supplies, it can adversely affect access to medically necessary patient care. The COVID-19 pandemic has highlighted the negative effect of prior authorization (PA) and step therapy on the delivery of care, particularly its impact on delayed care.

Prior authorization is a significant barrier to care that has harmed the patient-physician relationship. The AADA has long advocated for solutions that remove prior authorization policies that adversely affect patient care. For many skin diseases and conditions, medications are specialized and highly nuanced, and their efficacy is dependent on several patient factors. Prior authorization policies that place a third party, with no knowledge of the complexity or full history of a patient's condition, in a decision-making position are inappropriate, impede a patient's access to the most effective treatment, and cause delays that can harm patients. The clinically indicated choice of therapy should be respected and should rest on the patient-physician relationship where all critical factors—including efficacy and safety of all the treatment options, co-morbidities, and support system—are considered, fully discussed, vetted, and prescribed. Preserving the treatment decision between physicians and their patients should remain paramount; therefore, prior authorization and associated appeals policies should not encroach on or unduly burden physicians or patients in accessing optimal, medically necessary drug therapies.

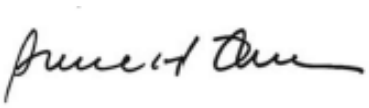
In 2016, the Academy conducted a survey of its members regarding the burden of prior authorizations. Over 90 percent of dermatologists reported experiencing an increase in the number of drugs requiring prior authorizations. Over 90 percent also cited prior authorizations as preventing or delaying treatment of their patients. More than two-thirds of dermatologists reported prior authorizations negatively affecting at least one patient per day. On average, dermatologists claim that they completed six prior authorizations a day, taking up to three hours each day. This is a

significant burden on dermatology practices, which are small businesses in their communities. Small and solo practices are forced to hire staff just to administer the prior authorizations for drugs and medical procedures. It is not just dermatologists who are impacted by the burden of prior authorizations. A study by Health Affairs revealed that when the time is converted to dollars, practices spent an average of $68,274 per physician per year interacting with health plans. This equates to $23 billion to $31 billion annually.[1] The majority of dermatologists report prior authorizations ultimately get approved after frequent provider appeals. Many describe the mechanism as a tool not to ensure medically necessary treatment, but rather a practice to exhaust providers in the hopes of them abandoning the recommended treatment for their patient. Prior authorization ultimately costs the health care system more than it saves, and furthermore, harms patient care. We urge HHS to take further action beyond the public health emergency to alleviate this burden both for ongoing care as well as in emergency situations.

Questions?

Please contact Leslie Stein Lloyd, lsteinlloyd@aad.org or 202-712-2614, if there are any questions about the recommendations in this letter. We appreciate the opportunity to work with HHS to ensure patients' access to high quality dermatologic care.

Sincerely,



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[1] https://www.healthaffairs.org/doi/full/10.1377/hlthaff.28.4.w533 Health Affairs, What Does It Cost Physician Practices To Interact With Health Insurance Plans? VOL. 28, NO. SUPPLEMENT 1: WEB EXCLUSIVES, 2009