

April 24, 2020

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Centers for Medicare & Medicaid Services,  
Department of Health and Human Services,  
Attention: CMS-1744-IFC  
P.O. Box 8016  
Baltimore, MD 21244-8016

Submitted online via [regulations.gov](https://www.regulations.gov)

**RE: Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency**

Dear Administrator Verma:

Established in 1943, the AAAAI is a professional organization with more than 7,000 members in the United States, Canada and 72 other countries. This membership includes allergist/immunologists (A/I), other medical specialists, allied health and related healthcare professionals—all with a special interest in the research and treatment of patients with allergic and immunologic diseases.

We appreciate the swift action you've taken to ensure clinicians, including A/I specialists, can continue to deliver important, medically necessary A/I care to our patients, including those who are most vulnerable to the community-wide outbreak, during the COVID-19 pandemic. Below, we provide feedback on the aforementioned interim final rule with comment (IFC).

**E/M Telehealth Services**

AAAAI greatly appreciates the new flexibilities afforded in the IFC and as part of 1135 waivers that have significantly improved access to telehealth services for beneficiaries during the public health emergency. Thus far, the A/I community experience with delivering virtual care and telehealth services has been positive. **We encourage CMS to consider implementing many of these temporary policies on a permanent basis.**

With respect to providing evaluation and management (E/M) services via telehealth, we share concerns with our colleagues in medicine that many beneficiaries either do not have audio/video communication devices, or they are declining "video" calls because they are unfamiliar or have concerns using this

**(more)**

component of their device. And, while CMS activated the telephone-only E/M services (i.e., CPT codes 98966-98968 and 99441-99443) for Medicare payment to address the need for “audio-only” E/M service delivery, the associated reimbursement is woefully inadequate and not reflective of the level of care being provided. To that end, ***we urge CMS to use its authority to waive the “video” requirement for furnishing office/outpatient E/M services (CPT 99201-99205 and 99211-99215) via telehealth.***

In the event CMS will not waive the “video” requirement, we urge the agency to increase reimbursement for the telephone E/M services to a level that is comparable with the office/outpatient E/M services.

#### Direct Supervision Revisions

A/I patients may receive physician-administered drugs for severe asthma, primary immune deficiency disease (PID), or other A/I conditions. Thus far, our patients have not reported challenges accessing these drug therapies in the office or other outpatient setting. Nevertheless, we appreciate that CMS has temporarily revised its direct supervision requirements to allow a “quarantined” physician to continue providing assistance and direction to in-person clinical staff using audio/visual technology. This will allow our patients to continue coming to the office-based infusion center to receive care from qualified clinical staff, including office-based infusions.

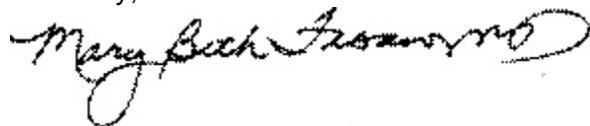
In the IFC, however, CMS also contemplates how its direct supervision requirements could facilitate at-home infusions whereby the physician’s clinical staff or a “hired” entity, such as a home health agency, would travel to a patient’s home to administer infused or injected medications. While we appreciate CMS’ goal of ensuring continued access to physician-administered drugs during the pandemic, we have concerns about certain drugs being administered in the home – that is, products that are currently not approved for in-home use, products with serious safety warnings, or products with the potential for adverse reactions that would be difficult to appropriately manage in the home by the physician’s clinical staff or their contractor. This could create serious risks for patients. Additionally, this significantly increases liability to the physician’s practice, especially when the standard of care does not normally contemplate administration of certain products outside the controlled setting of a medical facility.

***We urge CMS to be cautious in implementing this policy, and above all else, prioritize beneficiary safety.***

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We appreciate the opportunity to provide comments on the aforementioned issues of importance to our members. Should you have any questions, please contact Sheila Heitzig, Director of Practice and Policy, at sheitzig@aaaai.org or (414) 272-6071.

Sincerely,



Mary Beth Fasano, MD, MSPH, FAAAAI  
President, American Academy of Allergy, Asthma & Immunology