



March 25, 2020

Stephen M. Hahn, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue NW
Silver Spring, MD 20993

Re: Docket Number: FDA-2008-D-1106

Dear Commissioner Hahn:

On behalf of the American Academy of Family Physicians (AAFP), which represents 134,600 family physicians and medical students across the country, I write to urge your consideration for removing the current Risk Evaluation and Mitigation Strategy (REMS) and Element to Assure Safe Use (ETASU) status for prescription drugs that require in-person administration where treatment could take place through telehealth services and that physicians be held harmless for providing such services in accordance with current clinical guidelines.

As health professionals responding to the coronavirus crisis, we are concerned that patients' health and safety could be compromised. We were encouraged to see the recent Department of Justice guidance that allows physicians to use telehealth services as a proxy for an in-person visit for purposes of prescribing medications but its language requiring adherence with state laws is ambiguous and may not be sufficient. On March 22, the FDA issued [guidance](#) lifting REMS restrictions for lab testing and imaging studies to ensure patients are able to access treatment. Some state laws explicitly require in-person administration during a time when physicians are urged to curb unnecessary in-person visits. During this public health crisis, it is imperative that patients, especially those who are vulnerable or who live in rural areas, can use telehealth services to access needed care without unnecessary restrictions, particularly for medications that do not pose a risk of abuse or overdose.

Section 501-1 of the *Food, Drugs, and Cosmetics Act* (21 U.S.C. 355-1) indicates that the agency must evaluate if a drug's risks outweigh benefits. We urge the agency to issue waiver guidance that will allow doctors to be held harmless if they follow clinical recommendations that determine telehealth services can be safety treated as in-person visits for prescribing and administering drugs while the public health emergency is in effect. For more information, please contact Sonya Clay, Government Relations Representative, at 202-655-4905 or sclay@aafp.org.

Sincerely,

A handwritten signature in black ink, appearing to read "John S. Cullen".

John S. Cullen, MD, FAAFP
Board Chair

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