American College of Physicians
Leading Internal Medicine, Improving Lives

October 18, 2021

Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Re: Requirements Related to Air Ambulance Services, Agent and Broker Disclosures, and Provider Enforcement

Dear Administrator Brooks-LaSure:

On behalf of the American College of Physicians (ACP), I am pleased to share our comments on the Centers for Medicare and Medicaid Services' (CMS) Notice of Proposed Rulemaking regarding proposed rules implementing the No Surprises Act and the Consolidated Appropriations Act (2021). The College is the largest medical specialty organization and the second-largest physician group in the United States. ACP members include 161,000 internal medicine physicians (internists), related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum from health to complex illness.

I. CMS Enforcement of Group and Individual Insurance Market and Provider and Facility Requirements > State Enforcement

HHS Proposal:

Under the proposed rules, states' primary enforcement authority of Public Health Service (PHS) Act requirements over health insurance issuers would be extended to providers and facilities that furnish items or services to individuals in the state. HHS proposes that the same enforcement regime would apply to providers and facilities furnishing telehealth services. Under the rules, a state would be the primary enforcer of the PHS Act requirements against providers or facilities that provide services via telehealth to individuals located in the state, even in circumstances where the provider or facility is located in a different state.

HHS seeks comments on whether the approach taken in this proposed rule presents challenges with respect to providers or facilities furnishing telehealth services.

ACP Comments:

ACP believes that leaving primary enforcement of PHS Act requirements to states will create uncertainty and confusion among physicians and facilities providing telehealth services and will increase the chance of inconsistent application and enforcement of the PHS Act requirements. Under the proposed rule, a physician providing care to out-of-state patients can be subject to PHS Act enforcement by any number of states. As HHS notes, state licensure requirements have relaxed in response to the COVID-19 public health emergency. As a result, the provision of telehealth services, especially across state lines, has

increased significantly over the last year. Holding physicians accountable to multiple enforcers of the same requirement based on the location of the patient can lead to duplicative, burdensome compliance requirements.

Furthermore, it is not only possible but probable that patients will relocate over the course of their care, which means patients might not be located in the same state from visit to visit. This raises questions as to which state would be the designated enforcer of the PHS Act requirements for any given patient.

ACP believes that primary enforcement authority of PHS Act requirements for clinicians and "provider entities" of telehealth should be vested in HHS. Alternatively, HHS should consider changing the designated enforcing state from the state in which the individual (i.e., patient) is located to the state in which the physician is licensed to practice in order to mitigate some of the uncertainty associated with out-of-state enforcement.

II. CMS Enforcement With Respect to Providers and Facilities > Notice to Responsible Entities
HHS Proposal:
The PHS Act authorizes HHS to apply a civil money penalty with respect to a provider or facility that is found to be in violation of the Act. HHS proposes that CMS may conduct an investigation based on any information that indicates a provider or facility is failing to comply with PHS Act requirements. HHS specifies that, under the proposed rules, if CMS receives information that indicates a possible violation, or selects a provider or facility for investigation, or fails to receive data required under the PHS Act, CMS would provide a written notice to the provider or facility describing the information that prompted the investigation or notifying the provider or facility that it was selected for investigation, stating that a civil money penalty may be assessed, and that CMS may require a plan of corrective action. The notice would provide the date by which the provider or facility must respond with additional information, including documentation of compliance.

HHS anticipates that CMS would generally provide 14 days for providers and facilities to respond to the notice with the requested documentation. Furthermore, in circumstances that require a more immediate response, such as complaints involving urgent medical issues or allegations of fraud and abuse, CMS may shorten the time frame for the provider or facility to provide the requested documentation to within one day, or even less than 24 hours.

ACP Comments:
ACP believes it is not feasible for time-constrained clinicians to review the notice and substance of any allegations, assemble requested documentation, and draft a meaningful response to CMS within such a short time frame. As HHS noted, physicians will have to take a series of actions after receiving notice of an investigation or failing to comply with PHS Act requirements, including investigating the substance of the allegation, gathering the requested documentation and information, and formulating a response. ACP is concerned that the 14-day proposed time frame will be too brief and will create additional burdens for clinicians. ACP recommends extending this time frame to allow physicians and "provider entities" adequate time to review allegations, find information and documentation, and draft a response. **ACP suggests a 30-day time frame following a physicians' or facilities' receipt of notice would be more appropriate and will allow for more complete and substantiated responses from clinicians.** A 30-day time frame would be aligned with CMS's usual time frames and deadlines of 30 or 60 days for other matters. ACP believes the establishment of more consistent time frames for requests from physicians would help to reduce physician burden.

III. CMS Enforcement With Respect to Providers and Facilities > Amount of Penalty
HHS Proposal:
Under the proposed rules, HHS could impose a civil money penalty of up to $10,000 per violation if a provider or facility is found to be in violation of a PHS Act requirement. Such civil money penalties would be in addition to any other penalties prescribed or allowed by law.

HHS proposes that if CMS were to determine that it would impose a civil money penalty, several factors would be considered when determining the amount of the penalty, including (1) the nature of claims of noncompliance and the circumstances under which such claims were presented; (2) the degree of culpability of the provider or facility against which a civil money penalty is proposed; (3) the provider or facility's history of prior violations; (4) the frequency of the violation; (5) the level of financial and other impacts on affected individuals; and (6) any other matters as justice may require. HHS proposes that for every violation subject to a civil money penalty, if there are substantial or several mitigating circumstances, the aggregate amount of the penalty would be set at an amount sufficiently below the statutory maximum of $10,000 to reflect the mitigating circumstance.

As proposed in the rule, CMS would consider several factors as mitigating circumstances: (1) the provider or facility's record of prior compliance; (2) the gravity of the violation(s); and (3) if the provider or facility demonstrated that the violation was an isolated occurrence.

CMS would also consider certain factors to be aggravating circumstances: (1) if the frequency of violation indicates a pattern of widespread occurrence; (2) if the violation(s) resulted in significant financial and other impacts on the average affected individual(s), plan or issuer; or (3) if the provider or facility does not provide documentation showing that substantially all of the violations were corrected. HHS proposes that for every violation subject to a civil money penalty, if there are substantial or several aggravating circumstances, CMS may set the aggregate amount of the penalty at an amount sufficiently close to or at the $10,000 permitted by statute to reflect that fact.

HHS proposes that if certain criteria are met, CMS would waive a penalty. Penalties will be waived if the provider or facility does not knowingly violate and should not have reasonably known it violated the PHS Act, as long as the provider or facility withdraws any erroneous bill and, if necessary, reimburses the plan or enrollee, within 30 days of the violation.

HHS recognizes that there may be certain circumstances in which imposition of a civil money penalty would create a significant financial hardship for a provider or facility and proposes to create a hardship exemption to the civil money penalties that would otherwise be imposed for a violation of the PHS Act.

HHS seeks comments regarding this proposal, including examples of additional circumstances that may warrant a hardship exemption.

ACP Comments:
ACP appreciates that civil money penalties will be waived in certain circumstances and that CMS will consider exemptions when imposition of a civil money penalty would create significant financial hardship for a physician or facility. ACP is concerned, however, that a $10,000 penalty per violation is too extreme. Consequences of paying such high penalties per violation would hinder clinicians and practices from providing appropriate clinical care. In cases of multiple violations, the penalty can become outright prohibitive, especially for independent practitioners and small practices, potentially even forcing them to close their practice. **ACP recommends that HHS make the penalty a single, one-**

time payment not to exceed $5,000—not per violation. Alternatively, if HHS insists on moving forward with a per violation approach, ACP recommends reducing the penalty to a lesser amount per violation that still serves to incentivize compliance and deter violations.

Conclusion:

Thank you for this opportunity to comment on this HHS notice of proposed rulemaking regarding Requirements Related to Air Ambulance Services, Agent and Broker Disclosures, and Provider Enforcement. We are confident these recommended changes would improve the strength of these proposals and help promote access to affordable care for Medicare and Medicaid patients, while supporting physicians in their ability to deliver innovative care and protecting the integrity of the Medicare trust funds. We appreciate the opportunity to offer our feedback and look forward to continuing to work with the Agency to implement policies that support and improve the practice of internal medicine. Please contact Brian Outland, Director, Regulatory Affairs for the American College of Physicians, at boutland@acponline.org or 202-261-4544 with comments or questions about the content of this letter.

Sincerely,

William Fox, MD, FACP
Chair, Medical Practice and Quality Committee
American College of Physicians