

Sound Policy. Quality Care.

November 4, 2019

Seema Verma, MPH
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-6058-FC, Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Medicare, Medicaid, and Children's Health Insurance Programs; Program Integrity Enhancements to the Provider Enrollment Process

Dear Administrator Verma:

On behalf of more than 100,000 specialty physicians from 15 specialty and subspecialty societies, and dedicated to the development of sound federal health care policy that fosters patient access to the highest quality specialty care, the undersigned members of the Alliance of Specialty Medicine (the "Alliance") write in response to the above-referenced final rule with comment period issued by the Centers for Medicare and Medicaid Services (CMS).

The Alliance supports efforts that protect federal health care programs and the Medicare trust fund from fraud, waste, and abuse by unscrupulous providers. While we understand that statutory requirements and CMS' rule to require disclosure of affiliations seek to achieve this goal, we are concerned that the rule does not sufficiently balance concerns around administrative burden.

In the rule, CMS finalizes a "phased-in" approach to implementing new program integrity requirements for disclosure of affiliations with disclosable events, rather than requiring disclosures by every newly enrolling or revalidating provider or supplier. *The Alliance thanks CMS for this final policy, which significantly reduces burden for the majority of providers and suppliers who would otherwise be subject to the disclosure requirements.* At the same time, we are concerned that the finalized requirements are still overly burdensome, and that providers and suppliers, including specialty physicians, would experience significant difficulty in meeting disclosure requirements should they be required to report, contrary to CMS' goals under the Patients over Paperwork initiative. This is true both under the current rules that require dislosure upon request from CMS, as well as in future phases, where requirements would apply more broadly. Indeed, our physician members routinely report challenges with current Medicare enrollment requirements, which already impose a significant burden.

Layering new, highly complicated and far-reaching affiliation disclosure requirements on specialty physicians to participate in the Medicare program would erect new barriers to the practice of medicine and substantially increase compliance risk – factors that could discourage physicians from participating in Medicare and therefore reduce access to specialty care. Specifically, CMS finalized that, upon CMS request, providers and suppliers would be required to disclose any and all "affiliations" they had within the previous 5 years with a currently or formerly enrolled Medicare, Medicaid, or Children's Health Insurance Program (CHIP) provider or supplier that has ever had a "disclosable event." If CMS determines that any of the

disclosed affiliations poses an undue risk of fraud, waste, or abuse, then CMS would deny or revoke the provider's or supplier's Medicare enrollment. These requirements would apply even to physicians and other providers and suppliers that CMS has designated as having "limited categorical risk."

Under these final policies, many specialty physicians who are targeted for disclosure reporting will experience difficulty not only identifying and tracking affiliations for a rolling 5-year period, but also ascertaining whether such affiliations have been subject to disclosable events at any point in time — even prior to the start of the affiliation. While we recognize and appreciate that CMS has finalized a "reasonableness standard," whereby providers or suppliers would be required to report only if they knew or should reasonably have known of reportable data, we are concerned that the scope of reportable data is too broad and that there remains too much uncertainty regarding providers' and suppliers' obligations for collecting such data. Given these concerns, we urge CMS to carefully evaluate the usefulness of the data it collects during this initial phase, in order to determine whether changes can be made to reduce the scope of data required for reporting, particularly for providers and suppliers with the lowest risk.

Additionally, we ask CMS to work closely with stakeholders, including specialty physicians and other providers and suppliers of limited categorical risk, to develop subregulatory guidance for determining the extent to which they will have to investigate the existence of disclosable events among their affiliations.

With respect to CMS' request for public comment on operational approaches for obtaining affiliation information from providers and suppliers in future phases, the Alliance encourages CMS to pursue opportunities to minimize burden as much as possible, as well as to implement the phase-in gradually over time – even as long as 10 years or more. We urge CMS to prioritize collection of affiliation data from those providers and suppliers who present the greatest risk to the Medicare, Medicaid, and CHIP programs, and to limit data collection on physicians and other providers and suppliers with limited categorical risk. And even during these future phases, we urge CMS to continually assess the usefulness and actionability of data it receives from reporters, in order to further refine the data required, such that the benefits of finalized policies with respect to deterring fraud and abuse far outweigh the collective burden they will impose.

We appreciate the opportunity to share our recommendations for agency action, and look forward to a productive dialogue with the agency to ensure patients are truly prioritized over paperwork and have adequate access to specialty medical care. Should you have any questions, please contact us at info@specialtydocs.org.

Sincerely,

American Association of Neurological Surgeons
American College of Osteopathic Surgeons
American Gastroenterological Association
American Society of Cataract and Refractive Surgery
American Society of Plastic Surgeons
American Society of Retina Specialists
American Urological Association
Coalition of State Rheumatology Organizations
Congress of Neurological Surgeons
North American Spine Society
Society for Cardiovascular Angiography and Interventions