Alliance of Specialty Medicine

Sound Policy. Quality Care.

February 16, 2024

Dockets Management Staff
Food and Drug Administration
5630 Fishers Lane
Room 1061, (HFA-305)
Rockville, MD 20852

Submitted electronically via www.regulations.gov

RE: Draft Report and Plan on Best Practices for Guidance (Docket No. FDA-2023-N-5653)

The Alliance of Specialty Medicine (the "Alliance") represents more than 100,000 specialty physicians across 16 specialty and subspecialty societies. The Alliance is deeply committed to improving access to specialty medical care by advancing sound health policy. On behalf of the undersigned members, we write in response to the Food and Drug Administration (FDA) Draft Report and Plan on Best Practices for Guidance.

Use of Level 1 Guidance for Immediate Implementation

The Alliance appreciates that FDA, in conjunction with the release of the aforementioned draft report, is soliciting feedback from the public as it considers "*opportunities to streamline processes for regulatory submissions through the revision and issuance of guidance documents and to implement innovative guidance development processes and practices*."

As explained by the FDA, "*Level 1 guidance documents are guidance documents that include initial interpretations of a statute or regulation, changes in interpretation or policy that are of more than a minor nature, complex scientific issues, or highly controversial issues*," whereas "*Level 2 guidance documents describe existing practices or minor changes in interpretation or policy.*" FDA further highlights that "*public participation is directly solicited prior to the implementation of Level 1 guidance documents unless we determine that such prior public participation is not feasible or appropriate*," and points to its the issuance of such Level 1 guidances during the COVID19 public health emergency (PHE).

While we understand that, "*Issuing more guidance documents either as Level 1 guidance documents for immediate implementation…would allow FDA to allocate its limited resources more efficiently, which would help FDA keep pace with rapid scientific developments and better serve the public health*," and that "*the public may comment on any guidance at any time, including Level 1 guidance documents for immediate implementation,*" we disagree that the Agency should make more use of its authority to issue

Level 1 guidances. This is particularly true for Level 1 guidances because they "*include initial interpretations of a statute or regulation, changes in interpretation or policy that are of more than a minor nature, complex scientific issues, or highly controversial issues*."

Even if FDA guidance generally "*represents the current thinking of the Food and Drug Administration (FDA or the Agency)*" and "*does not create any rights for any person and is not binding on FDA or the public*," such documents are relied on by stakeholders to ensure compliance and frequently cited during FDA inspections, legal proceedings, and in other venues. Without prior notice-and-comment, it would be difficult, if not impossible, for FDA to fully appreciate how its guidances may impact affected stakeholders, including patients. Further, issuing more Level 1 guidance without advance notice-and-comment does not align with the Biden Administration's efforts to improve public engagement in similar processes (i.e., rulemaking) as outlined in various Executive Orders.

The Alliance urges FDA to prioritize advance notice-and-comment when issuing Level 1 guidances. FDA should also include detailed examples and rationale of when Level 1 guidance may necessitate implementation without advance notice-and-comment, in addition to the COVID-19 PHE examples provided.

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We appreciate the opportunity to comment on these important issues and welcome the opportunity to meet with you to discuss them in more detail. Should you have any questions or wish to schedule a meeting, please contact us at info@specialtydocs.org.

Sincerely,

American Academy of Facial Plastic and Reconstructive Surgery
American Academy of Otolaryngology-Head and Neck Surgery
American Association of Neurological Surgeons
American College of Mohs Surgery
American Gastroenterological Association
American Society for Dermatologic Surgery Association
American Society of Cataract and Refractive Surgery
American Society of Echocardiography
American Society of Plastic Surgeons
American Society of Retina Specialists
American Urological Association
Coalition of State Rheumatology Organizations
Congress of Neurological Surgeons
National Association of Spine Specialists
Society of Interventional Radiology