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September 16, 2020

By Electronic Submission via www.regulations.gov

The Honorable Alex M. Azar II
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: HHS-OS-2020-0008-0002: Proposed Rule Regarding Department of Health and Human Services Good Guidance Practices

Dear Secretary Azar:

On behalf of the members of the Advanced Medical Technology Association (AdvaMed), we write to provide comments in response to the proposed rule (Proposed Rule) regarding the Department of Health and Human Services (HHS) good guidance practices at 85 Fed. Reg. 51396 (August 20, 2020).

I. INTRODUCTION

AdvaMed is a trade association representing the world's leading innovators and manufacturers of medical devices, diagnostic products, digital health technologies, and health information systems. Together, our members manufacture much of the life-enhancing and life-saving health care technology purchased annually in the United States and globally. AdvaMed members range from the largest to the smallest medical technology producers and include hundreds of small companies with fewer than 20 employees. Our members are committed to developing new technologies and services that allow patients to lead longer, healthier, and more productive lives. The devices made by AdvaMed members help patients stay healthier longer and recover more quickly after treatment and enable clinicians to detect disease earlier and treat patients as effectively and efficiently as possible.

II. COMMENTS

A. In General

AdvaMed commends the spirit of the proposed rule and its general framework, as it establishes requirements and a process for issuing and maintaining guidance, which promotes clarity about the full field of guidance in effect and the limitations on how such guidance may be used. We applaud the establishment of formal public notice-and-comment obligations for significant guidance documents. AdvaMed welcomes HHS's efforts to increase accountability, improve the

fairness of guidance issued by the Department, guard against unlawful regulation through guidance, and safeguard the important principles underlying the United States administrative law system.

We commend the application of administrative law principles to HHS guidance and the Administration's efforts to ensure that guidance may not be issued to (a) establish legal obligations that are not reflected in duly enacted statutes or the regulations lawfully promulgated under them, or (b) require regulated entities to take any action or to refrain from taking any action beyond what is already required by the terms of an applicable statute or regulation.

B. Proposed Rule §1.2: Definition of "Guidance Document"

1. Eliminate the Ambiguity Concerning the "Policy" Requirement and the Application of the Third Part of the Definition

The Proposed Rule definition of "Guidance Document" includes the following:

> *Guidance document* means [1st part:] any Department statement of general applicability, [2nd part:] intended to have future effect on the behavior of regulated parties and [3rd part:] which sets forth a policy on a statutory, regulatory, or technical or scientific issue or an interpretation of a statute or regulation.[1]

We are concerned about the ambiguities that may arise in the application of the third part of the definition, which specifies that a Guidance Document "sets forth a policy on a statutory, regulatory, or technical or scientific issue or an interpretation of a statute or regulation."

The preamble of the Proposed Rule states:

> The hallmark of guidance is that it includes statements of general applicability intended to govern the future behavior of regulated parties. Thus, agency releases of technical or scientific information would not constitute guidance unless *also accompanied by a policy on or related to* that technical or scientific information that is intended to affect the future behavior of regulated parties.[2]

The preamble statement above seems to introduce a limitation that is not apparent from the plain reading of the definition. More specifically, the portion that states "or an interpretation of a statute or regulation" does not appear to be an alternative to the "policy" means of satisfying the third part of the definition when the "Department statement" is technical or scientific information. For example, the communication of technical information that demonstrates limitations in how

[1] 85 Fed. Reg. 51396, 51400 (Aug. 20, 2020) (emphasis added).

[2] 85 Fed. Reg. 51396

regulated entities should interpret a regulation would not appear to meet the definition of "Guidance document."

When the third part of the definition is read in light of the preamble statement above, one reasonable interpretation is that the "policy" requirement stands independent of the communication of technical or scientific information. "Policy" is not defined in the Proposed Rule, which could allow for interpretations that would enable a guidance document to evade the Proposed Rule safeguards. Dictionary definitions for policy include:

- a definite course or method of action selected from among alternatives and in light of given conditions to guide and determine present and future decisions
- a high-level overall plan embracing the general goals and acceptable procedures especially of a governmental body
- a set of guidelines or rules that determine a course of action
- an overall plan, principle, or guideline[3]

Using one of the last three definitions of policy above would appear to expand the "policy" requirement in the Proposed Rule definition of "Guidance document" such the agency release of technical information that interprets a regulation would also need to specify a plan, guideline, or principle concerning the technical information that is intended to affect the future behavior of regulated parties.

Given the ambiguities and potential loophole the term "policy" may create, we agree with one commenter's proposal to replace "policy" with "expectation." Using "expectation" instead is a sound approach to addressing this potential confusion, which should also mitigate the possible avoidance of the intended obligations in the Proposed Rule. We agree that using "expectation" would make it clearer that any statement that imparts an expectation of the agency concerning the performance of the regulated parties would be deemed a Guidance Document and subject to the safeguards in the Proposed Rule.

To clarify further to this end, the third part of the definition should explicitly denote that it may be satisfied by either an expectation or an interpretation of a statute or regulation. We recommend modifying the first sentence of the definition as follows:

> *Guidance document* means any Department statement of general applicability, intended to have future effect on the behavior of regulated parties and which sets forth either (a) ~~a policy~~ an expectation on a statutory, regulatory, or technical or scientific issue or (b) an interpretation of a statute or regulation.

[3] "Policy." Merriam-Webster.com Dictionary, Merriam-Webster, https://www.merriam-webster.com/dictionary/policy. Accessed 11 Sep. 2020.

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2. HHS OIG Advisory Opinions

The last two sentences of the proposed definition of "Guidance Document" are:

> Pre-enforcement rulings, *i.e.*, communications with a person that interpret or apply the law to a specific set of facts, such as letter rulings, advisory opinions, no-action letters, and notices of noncompliance, do not constitute guidance documents. If, however, the Department issues such a document that on its face is directed to a particular party, but the content of the document is designed to guide the conduct of other regulated parties, such a document would qualify as guidance.[4]

HHS Office of Inspector General (OIG) Advisory Opinions include content that appears to be designed to guide the conduct of regulated parties other than the requestor by setting forth OIG's interpretation of statutes and regulations. Accordingly, Advisory Opinions should meet the definition of Guidance Document under the Proposed Rule. Applying certain requirements under the Proposed Rule to Advisory Opinions would be welcome. For example, integrating Advisory Opinions into the fully text-searchable Guidance Repository and allowing Advisory Opinions to be eligible for the Procedure to Petition for Review of Guidance (in so far as the Advisory Opinions' applicability to regulated entities other than the requester) would help ensure no unintended burdens are placed on companies, especially for those with fewer resources.

C. Proposed Rule § 1.3: Requirements for Department Issuance and Use of Guidance Documents

AdvaMed supports the requirements and processes specified in section 1.3. We welcome the proposed process for soliciting and responding to public comments concerning proposed versions of Significant Guidance Documents.

D. Proposed Rule § 1.4: Guidance Repository

AdvaMed enthusiastically endorses the creation of a Guidance Repository that is fully text searchable. All text within the Guidance Documents themselves should be included in the text search function. If a Guidance Document includes image, video, or audio formats, transcriptions should also be made available and be included in the text search functionality. AdvaMed supports the required notifications and disclaimers and the use of the repository for the notice and comment process.

E. Proposed Rule § 1.5: Procedure to Petition for Review of Guidance

AdvaMed commends the proposed procedure to allow interested parties to petition the Department to review a Guidance Document.

[4] 85 Fed. Reg. 51396, 51400 (Aug. 20, 2020)

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Thank you in advance for your consideration of our comments and proposals. We would be pleased to discuss any aspect of our comments in greater detail at your convenience. Please do not hesitate to contact me at (202) 783-8700 or cwhite@advamed.org with any questions.

Sincerely,

/s/

Christopher L. White
Chief Operating Officer and General Counsel
Advanced Medical Technology Association (AdvaMed)