Association for Pathology Informatics

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Re: 86 FR 4088 - Making Permanent Regulatory Flexibilities Provided During the COVID-19 Public Health Emergency by Exempting Certain Medical Devices From Premarket Notification Requirements

March 15, 2021

To Whom It May Concern:

The Food and Drug Administration's Federal Register (FR) Notice of January 15, 2021, proposes, in part, to exempt 83 class II devices from premarket review as required under section 510(k) of the Food, Drug, and Cosmetic Act. Amongst the product codes listed in Table 6 of the Notice ("Class II Devices and Unclassified Devices Proposed Exempt from 510(k) Requirement") are several that comprise core components of digital pathology systems. As requested in the Notice, the Association for Pathology Informatics (API) herein provides its insights, recommendations, and requests for comment on this proposal.

API is the only national organization dedicated exclusively to the development and practice of pathology informatics. It plays a critical role in enabling and empowering informatics to meaningfully contribute to the provisioning of safe, effective, and efficient patient care. To this end, the API supports both clinical practice and innovation in pathology informatics through research, education, and advocacy. Moreover, the API plays an active role in contemporary legal, ethical, social, and regulatory issues related to pathology informatics. It counts amongst its membership many world leaders in their respective informatics subspecialties. API also maintains and seeks to develop further relationships with other professional societies and industry partners with similar interests and goals.

The Association of Pathology Informatics aligns with the FDA's priorities in risk management, interoperability, and standardization. We fully support the direction behind this FR Notice as it relates to digital pathology devices. More broadly, API supports the FDA's recent efforts to establish a more agile and adaptive regulatory framework that can keep pace with accelerating medical innovation. Within that framework, we seek to provide the FDA with continuous feedback as part of the larger community of early adopters of digital and computational pathology technologies and clinical workflow models.

Before the COVID-19 Public Health Emergency (PHE), regulation of digital pathology devices contributed to the greatly delayed deployment and lower adoption rate in the United States than nations operating under different and much less restrictive regulatory domains (e.g., Canada, the European Union, and Japan). Likewise, this regulatory framework required end-to-end evaluation of Whole Slide Imaging (WSI) systems until recently. This approach meant that each component of the overall image pipeline was tied to monolithic configurational approval. The consequence was the prevention of device substitution, even when new components with superior performance became available.

One result of the pandemic was a pivot toward telemedicine, with pathology being one of the specialties actively seeking to leverage remote diagnostic technologies' benefits. About 6% of pathologists used digital pathology devices for remote diagnosis (i.e., telepathology), which allowed them to facilitate continuity of care while protecting pathologists and laboratory staff's health (*reference: COVID-19 Pathologist Impact Survey: Summary of Findings. October 2020*). This practice model was under many state directives, which stipulated that remote sign-out work is feasible and should be carried out remotely, when possible, to curb the horizontal transmission of SARS-CoV-2.

As of April 2020, in consonance with these COVID-19 PHE protective efforts, the FDA issued its guidance on remote digital pathology devices, which permitted modification to FDA-cleared digital pathology devices and the marketing of non-510(k)-cleared digital pathology devices intended for telepathology. This relaxation of oversight, along with the Centers for Medicare & Medicaid Services (CMS) Memorandum of March 26, 2020, afforded laboratories the autonomy and flexibility to respond to the crisis by assembling digital pathology systems, using carefully-selected:

1. Consumer off-the-shelf (COTS) computer monitors
2. Research use only (RUO) slide scanners
3. Any other interoperable components required for digital pathology sign-out

A valuable byproduct of this forced experiment was a large body of real-world experiential feedback regarding the safe application of digital pathology for patient care and the concurrent accumulation of a wealth of operational knowledge concerning how effectively to use such modular solutions. The attached document is our best attempt to summarize the findings and opinions of our members.

To briefly summarize API's feedback: We support continuing FDA oversight to varying degrees for the digital pathology product codes QKQ, PSY, and OEO. By contrast, based on our members' vital feedback, we believe that FDA oversight of the digital pathology product code PZZ (digital pathology display) is no longer required. Detailed comments and recommendations for each of these digital pathology product codes are in the attached document.

Moreover, API's stated position, in this cover letter and the attached document, has the endorsement of four leading pathology organizations:

American Society for Clinical Pathology

Association of Directors of Anatomic and Surgical Pathology

Association of Pathology Chairs

COLLEGE of AMERICAN PATHOLOGISTS

API is thankful for the endorsement of these leading pathology organizations and the opportunity to comment on these specific product code decisions, which are critical to our field's future. More broadly, we are grateful to work with the Department of Health and Human Services to pursue our shared interest and provide the United States citizens with the highest possible healthcare standard.

Sincerely,

S. Joseph Sirintrapun, M.D.

On behalf of the Association for Pathology Informatics Governing Council