Remote work update

PIcc Steering Committee Meeting 3/29/2023 – J Lennerz

Pandemic as an enabler

- National, state, and federal requirements are different after the pandemic
  - Pandemic as enabler

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

CMS CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality/Survey & Certification Group

Ref: QSO-20-21-CLIA

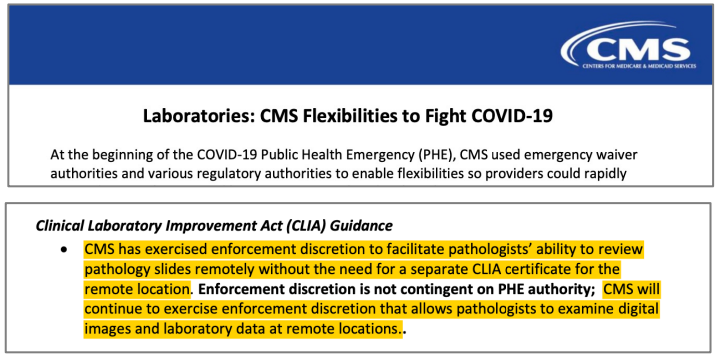
DATE: **March 26, 2020**

TO: State Survey Agency Directors

FROM: Director
Quality, Safety & Oversight Group

SUBJECT: Clinical Laboratory Improvement Amendments (CLIA) Laboratory Guidance During COVID-19 Public Health Emergency

Memorandum Summary



CMS

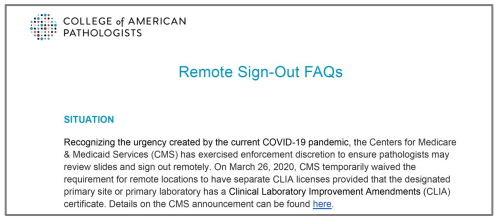
Laboratories: CMS Flexibilities to Fight COVID-19

At the beginning of the COVID-19 Public Health Emergency (PHE), CMS used emergency waiver authorities and various regulatory authorities to enable flexibilities so providers could rapidly

Clinical Laboratory Improvement Act (CLIA) Guidance

- CMS has exercised enforcement discretion to facilitate pathologists' ability to review pathology slides remotely without the need for a separate CLIA certificate for the remote location. **Enforcement discretion is not contingent on PHE authority;** CMS will continue to exercise enforcement discretion that allows pathologists to examine digital images and laboratory data at remote locations..

  - Professional societies (e.g., *College of American Pathologists*)



COLLEGE of AMERICAN PATHOLOGISTS

Remote Sign-Out FAQs

SITUATION

Recognizing the urgency created by the current COVID-19 pandemic, the Centers for Medicare & Medicaid Services (CMS) has exercised enforcement discretion to ensure pathologists may review slides and sign out remotely. On March 26, 2020, CMS temporarily waived the requirement for remote locations to have separate CLIA licenses provided that the designated primary site or primary laboratory has a Clinical Laboratory Improvement Amendments (CLIA) certificate. Details on the CMS announcement can be found here.

- **Requirement:** Establish and maintain a "valid and active CLIA certificate" (for offer letter; so-called "home certificate" CMS-116 => multiple sites under MGH main license)

Refer to “CLIA Waiver* Project”

CLIA Waiver* Project

Continued Enforcement Discretion For Remote Review

**The term "CLIA waiver" now belongs to the jargon for remote review during the public health emergency; however, the term 'waiver' is inaccurate. CMS (and the CLIA program) are unable to approve so-called "section 1135 waiver requests". The section 1135 waiver authority is only applicable to specified programs (or penalties) authorized by the Social Security Act (SSA). The CLIA program does not fall into this category of programs.*

https://pathologyinnovationcc.org/projects/clia-waiver-project

Memorandum

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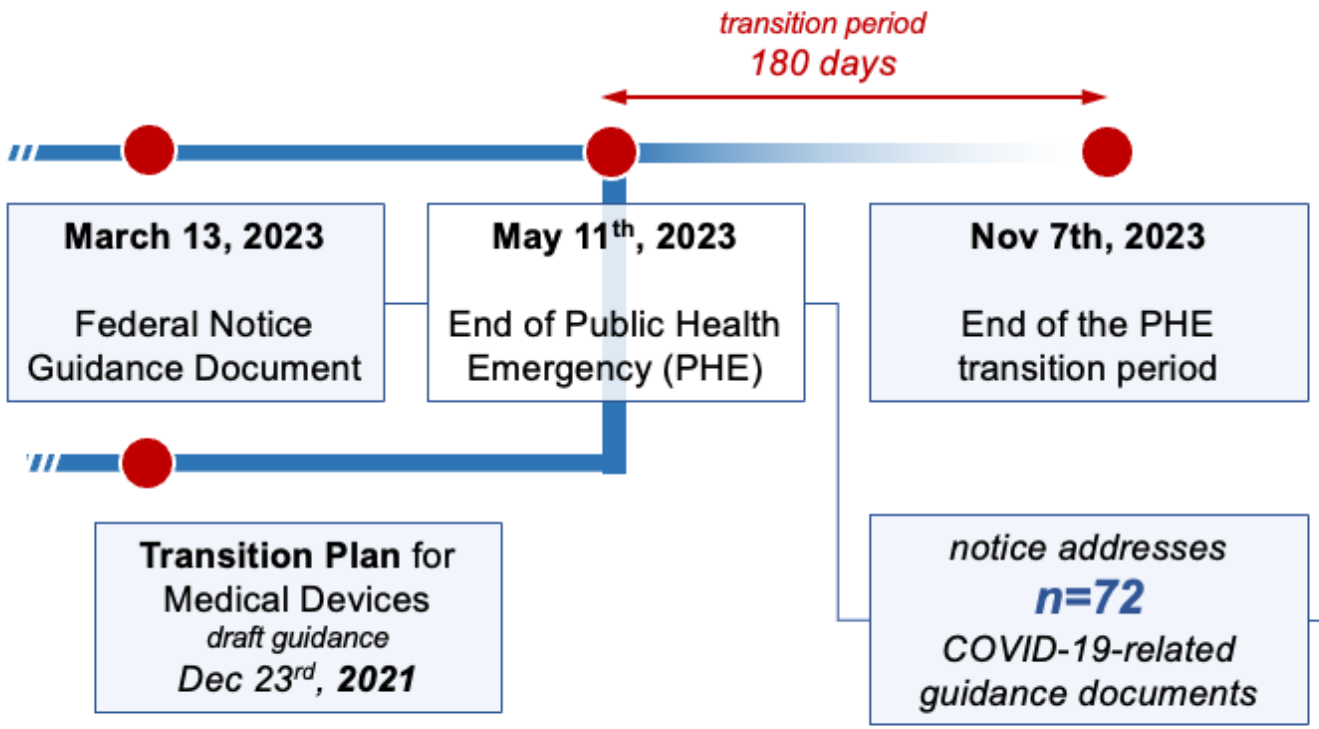
Pandemic comes to an end. Federal Notice from March 13, 2023

Q: What happens when the public health emergency ends on May 11th, 2023 ?

Answer: Transition plan



Overview of guidance documents

Table 1: **no longer** be in effect

n=22

Table 2: remain for 180d, **then discontinued**

n=22

Table 3: remain for 180d, then **further revision**

n=24

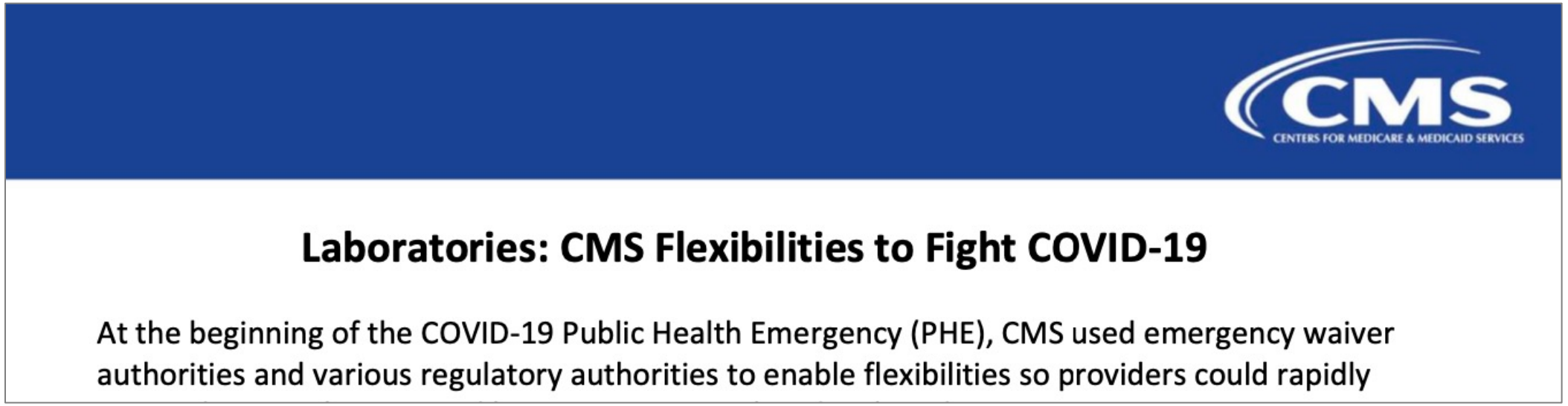
Table 3: **remain** in effect

n=4

Joe Lennerz (CID) 2023

Focus on Remote + Digital Pathology

- CMS guidance from February 2023



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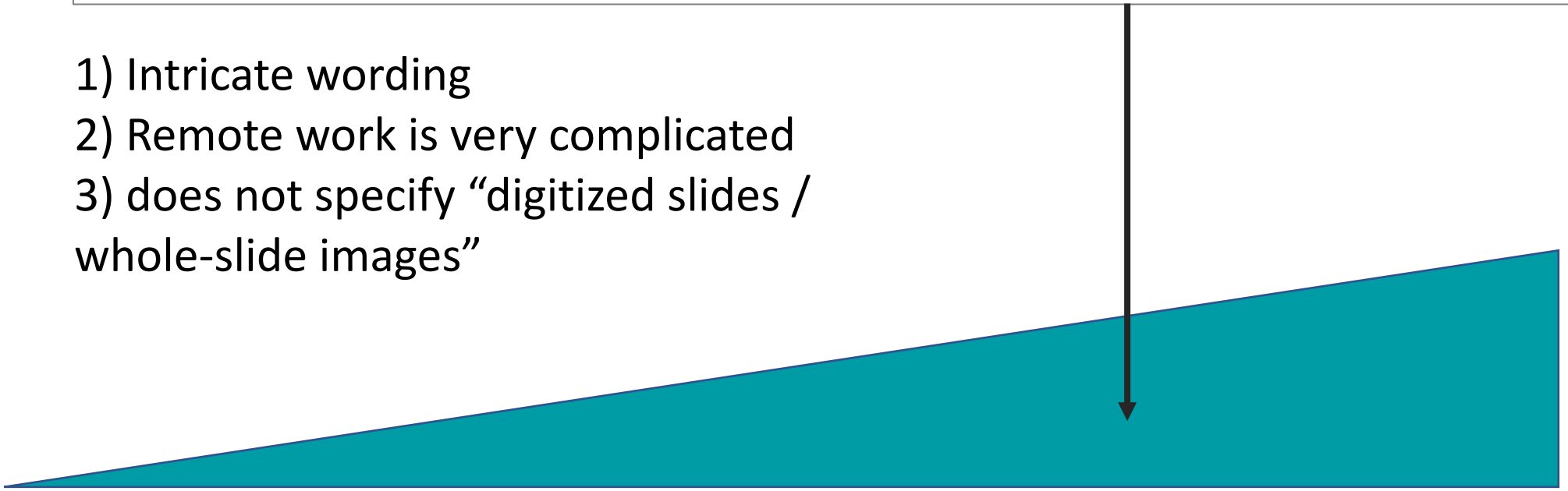
1) Intricate wording
2) Remote work is very complicated
3) does not specify "digitized slides / whole-slide images"



Relative Regulatory Complexity

Electronic remote sign-out "home key out"

Electronic remote Review and sign-out "home key out"

Electronic remote Review images/lab-data "home key out"

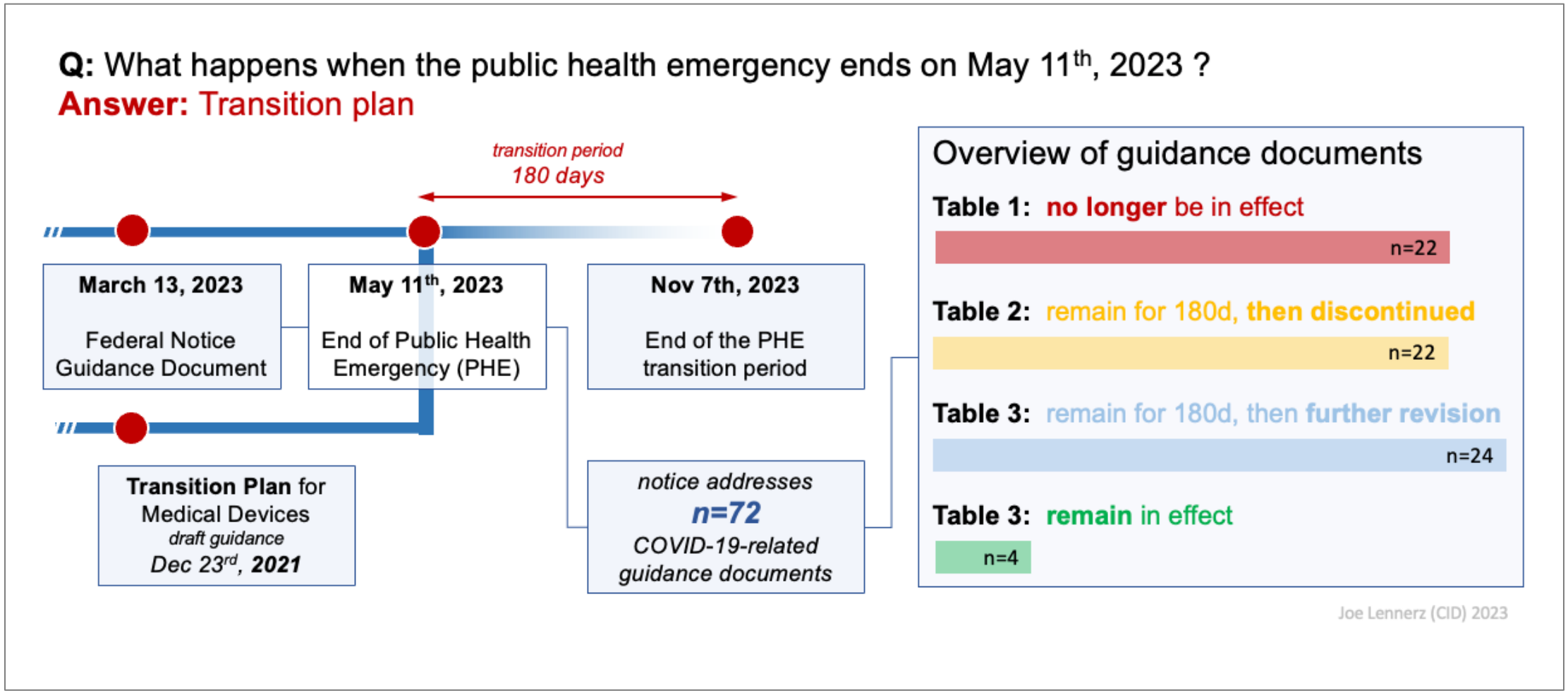
- Glass slides
- Digitized
- Remote s/o
- Primary Dx

Federal Notice Table 2

TABLE 2—GUIDANCE DOCUMENTS FDA IS REVISING TO CONTINUE IN EFFECT FOR 180 DAYS AFTER THE COVID–19 PHE DECLARATION EXPIRES

Docket No.	Lead center	Title of guidance
FDA–2020–D–1136	CDER	Policy for the Temporary Use of Portable Cryogenic Containers Not in Compliance With 21 CFR 211.94(e)(1) For Oxygen and Nitrogen During the COVID–19 Public Health Emergency Guidance for Industry.
FDA–2020–D–1136	CDER	Manufacturing, Supply Chain, and Drug and Biological Product Inspections During COVID–19 Public Health Emergency Questions and Answers.
FDA–2020–D–1106	CDER	Policy for Certain REMS Requirements During the COVID–19 Public Health Emergency Guidance for Industry and Health Care Professionals.
FDA–2020–D–1138	CDRH	Enforcement Policy for Remote Digital Pathology Devices During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency.*
FDA–2020–D–1138	CDRH	Enforcement Policy for Imaging Systems During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency.*
FDA–2020–D–1138	CDRH	Enforcement Policy for Non-Invasive Fetal and Maternal Monitoring Devices Used to Support Patient Monitoring During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency.*
FDA–2020–D–1138	CDRH	Enforcement Policy for Telethermographic Systems During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency.*
FDA–2020–D–1138	CDRH	Enforcement Policy for Digital Health Devices for Treating Psychiatric Disorders During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency.*
FDA–2020–D–1138	CDRH	Enforcement Policy for Extracorporeal Membrane Oxygenation and Cardiopulmonary Bypass De-

What's next


Q: What happens when the public health emergency ends on May 11th, 2023 ?
Answer: Transition plan
transition period
180 days
March 13, 2023
Federal Notice
Guidance Document
May 11th, 2023
End of Public Health
Emergency (PHE)
Nov 7th, 2023
End of the PHE
transition period
Transition Plan for
Medical Devices
draft guidance
Dec 23rd, 2021
notice addresses
n=72
COVID-19-related
guidance documents
Overview of guidance documents
Table 1: no longer be in effect
n=22
Table 2: remain for 180d, then discontinued
n=22
Table 3: remain for 180d, then further revision
n=24
Table 3: remain in effect
n=4
Joe Lennerz (CID) 2023

Approach 1 – specific rules

Contains Nonbinding Recommendations

Enforcement Policy for Remote Digital Pathology Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency

Guidance for Industry, Clinical Laboratories, Healthcare Facilities, Pathologists, and Food and Drug Administration Staff

April 2020

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health (CDRH)
Office of Product Evaluation and Quality (OPEQ)

III. Scope

The enforcement policy described in this guidance applies to the following devices ("digital pathology devices"), which may be used during the COVID-19 public health emergency, when they are intended for use in remote reviewing and reporting of digital pathology slides:

Table 1

Classification Regulation	Device Type	Product Code[3]	Class
21 CFR 864.1860	Automated Digital Image Manual Interpretation Microscope	OEO	II
21 CFR 864.3700	Whole Slide Imaging System	PSY	II
21 CFR 864.3700	Digital Pathology Image Viewing and Management Software	QKQ	II
21 CFR 864.3700	Digital Pathology Display	PZZ	II

Although the digital pathology devices listed above are typically used in clinical laboratories, hospitals, and other healthcare facilities, as further discussed in Section IV below, many of these devices possess the capability for reviewing and reporting of digital pathology slides from remote locations.

Approach 2 – guidance

Contains Nonbinding Recommendations

Draft – Not for Implementation

Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This draft guidance document is being distributed for comment purposes only.

Document issued December 2021.

You should submit comments and suggestions regarding this draft document within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions about this document, contact the Regulation, Policy, and Guidance Staff at RPG@fda.hhs.gov.

FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES & RADIOLOGICAL HEALTH

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

III. Scope

This guidance applies to devices that fall within the enforcement policies described in the guidances identified in List 1 below.[8, 9]

List 1

- Enforcement Policy for Remote Digital Pathology Devices During the COVID-19 Public Health Emergency[10]
- Enforcement Policy for Imaging Systems During the COVID-19 Public Health Emergency[11]
- Enforcement Policy for Non-Invasive Fetal and Maternal Monitoring Devices Used to Support Patient Monitoring During the COVID-19 Public Health Emergency[12]
- Enforcement Policy for Telethermographic Systems During the COVID-19 Public Health Emergency[13]

(1) Recommendations for Transition Implementation Plan

We expect that some marketing submissions will include changes or updates to the device and/or its labeling compared to the product that was distributed during the COVID-19 PHE prior to Phase 3, and in some cases, a manufacturer may not receive a positive decision from FDA on its marketing submission. To help address such situations efficiently, we recommend that manufacturers include with their marketing submissions a proposed "transition implementation plan" that addresses the manufacturers' plans for devices already distributed in the case of a positive decision or a negative decision on the marketing submission. We recommend that this include the following information, as applicable:[51]

- Estimated number of devices that fall within the policies outlined in any of the guidances referenced in List 1 above that are currently in U.S. distribution;

Approach 3 – regulatory science approach

- PIcc (in conjunction with MDIC) will organize a meeting
  - PIcc23
  - In-person meeting with all key stakeholders
  - Details: see 3/29/2023 meeting summary
- Established regulatory science approaches
- Provide resources

- Discussion

Remote work update

PIcc Steering Committee Meeting 3/29/2023 – J Lennerz