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Subject: Docket ID HHS-OS-2020-0016: Regulatory Relief to Support Economic Recovery; Request for Information (RFI)

To Whom It May Concern:

The Advanced Medical Technology Association ("AdvaMed") appreciates the opportunity to provide comments on the Department of Health and Human Services' ("HHS") Request for Information concerning Regulatory Relief to Support Economic Recovery ("RFI").[1] AdvaMed represents manufacturers of medical devices, digital health technologies, and diagnostic products that transform health care through earlier disease detection, less invasive procedures, and more effective treatment. Our members range from the smallest to the largest medical technology innovators and companies.

The United States has taken unprecedented steps to respond to the COVID-19 public health emergency ("PHE"). Myriad Federal and state laws, regulations, and policies—including those issued by HHS and its agencies—have been implemented, revised or repealed to enable the private sector's ability to respond effectively. These actions assisted the medical technology industry's response to mobilize quickly and efficiently to support patient care, public health and health care providers. Almost overnight the industry refocused its operations and expanded production and capacity to develop and manufacture the medical technologies that are critical to our country's fight against the pandemic and arm health care workers on the frontlines with the tools they need to save lives.

To ensure patients and healthcare providers continue to benefit from these actions, we provide below our recommendations for key HHS policies, organized by agency, that have made an impact on our industry. Importantly, and consistent with the Administrative Procedures Act ("APA"), we believe any agency withdrawing or changing a COVID-19-related policy must provide stakeholders reasonable notice and set out a transition plan with opportunity to comment. Agency policy changes should be made only upon fair advance notice and opportunity to share impact and comments.

[1] Regulatory Relief to Support Economic Recovery; Request for Information (RFI), 85 Fed. Reg. 75720 (Nov. 25, 2020), *available at* https://beta.regulations.gov/document/HHS-OS-2020-0016-0001.

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I. Centers for Medicare & Medicaid Services

A. Telehealth/Remote Monitoring and Face-to-Face Requirements

With waiver authority provided by Congress at the onset of the pandemic, the Centers for Medicare & Medicaid Services ("CMS") took a bold approach to ensure that Medicare beneficiaries have access to health care services during the PHE through telehealth, telemedicine, and other communication-based technology services such as remote patient monitoring. It has done so by waiving statutory and regulatory requirements that limit the location, eligible providers, and types of technologies authorized for Medicare beneficiaries to receive telehealth. CMS also has relaxed certain coverage criteria for services that would require in-person visits to a physician's office to allow telehealth visits to substitute for these in-person visits. Similar expansions of remote patient monitoring and other communication-based technology services have been put in place by CMS during this time.

Since the early months of the PHE, CMS has more recently proposed and finalized additional expansions of telehealth and communication-based technology services through its CY 2021 update to the Physician Fee Schedule Rule. The rule eliminates, on a permanent basis and not just during the PHE, the prohibition on the use of smart devices for telehealth through an amendment to an existing Medicare regulation. The agency has also implemented a new mechanism for making certain telehealth services, which have been added to the Telehealth Services List on a temporary basis, to be covered under a new Category 3 to allow services to be covered during the PHE and through the calendar year when the PHE ends. The extended period of coverage beyond the PHE is intended to provide flexibility for sponsors of the temporary additions to gather evidence and data for making the case that the services should be added to the list on a permanent basis.

With these expansions during the PHE, telehealth and other covered technology-based services have demonstrated the effectiveness of telehealth and other communication-based services as important sources of care for beneficiaries, particularly for the growing number of frail patients aged 85 and over with multiple chronic conditions. The immediate uptake of telehealth and other services has also demonstrated the agility of the healthcare system to scale up to provide these services, and in the process has transformed the delivery system by leveraging innovative technologies that can improve health outcomes and reduce overall health care spending.

Together these expansions, the enhanced access to care they have provided, and ability of the healthcare system to respond to meet the challenges of providing care during the pandemic should lead CMS to review its regulations and coverage policies to determine how existing policies can and should further be changed to accommodate coverage of new modes of care delivery. At a minimum, the expansions of telehealth and other technology-based services should continue through the end of the calendar year when the PHE ends. We recommend that CMS continue the extension beyond the year in which the PHE ends to allow sufficient time for evidence to be fully developed on the value of these telehealth services. We also strongly urge CMS to support legislative changes to Medicare statute that would eliminate prohibitions on Medicare telehealth services being provided in urban areas and in a patient's

home on a permanent basis.

B. Hospitals-without-Walls ("HwoW")

The HwoW program allows ambulatory service centers ("ASC") and other non-hospital settings to serve as "hospitals" during the PHE. These changes have been valuable in providing patients safe access to care outside of traditional hospital settings as the pandemic has continued.

While the ability to transition hospitals to ASCs has been helpful in managing care during the PHE, and in potentially limiting patient exposure to COVID-19, we believe that these services should not be made permanent until we can assure that proper safety parameters and payment mechanisms are in place. Instead, AdvaMed recommends that CMS develop a mechanism for phasing out the participation of facilities that have converted their ASCs to outpatient departments as part of the HwoW program as turning these services "off" immediately, at the conclusion of the PHE, could be problematic. A transition period will be needed to ensure patient safety and health and to return these facilities back to normal, pre-PHE operation.

The HwoW program has also led to the expansion of care to patient homes. The Acute Care at Home program enables patients who would otherwise have to seek care in an emergency department or inpatient setting to receive this care in their home. This care option is currently available for 60 conditions. AdvaMed asks CMS to carefully monitor data from this program to assess whether it should be made permanent at a future time. During the PHE we have seen the benefit and utility of telehealth and telemedicine services in not only protecting patients but in providing a viable means for obtaining health care for patients, for whom a trip to a hospital (due to infirmity, distance, and other factors) may not be convenient or safe. AdvaMed also recommends that CMS work with stakeholders to identify other services that should be added to the acute care at home program and as the Agency considers the development and implementation of policies effecting the future of the program.

C. Expanded Ordering Privileges

Order privileges for SARS/COV2 virus testing were expanded to allow all practitioners to order tests up to the scope of their state license, allowing pharmacists and other practitioners in many states to order tests. This policy should remain in place after the PHE, and potentially be expanded to include other tests.

D. Onsite Testing and PPE Access

Testing and access to PPE to identify and maintain COVID-19 and COVID-19-free sites will be critical for expanding service delivery for non-COVID-19 surgeries, procedures, and treatments.

E. Coverage of Serology Testing Under Medicare

Continuation of coverage of all COVID-19 tests, including molecular, antigen and serology

(antibody) testing in a range of care settings, under Medicare Parts A & B, including inpatient, outpatient, and other ancillary settings, will be critical to fighting COVID-19 even after the PHE concludes. Additionally, HHS, Labor and Treasury should specify that ERISA and other plans must cover serology testing, both during and after the PHE, for purposes of public health and potentially for vaccine distribution.

F. Coverage of Testing With No Cost-Sharing

Plans and issuers should continue to cover COVID-19 testing without cost-sharing (including deductibles, copayments, and coinsurance), prior authorization requirements, or other medical management requirements for these items and services when determined to be medically appropriate.

G. New HCPCS Codes For Medicare Payment For Specimen Collection

Medicare should continue to pay independent laboratories the nominal payment amounts that were established for specimen collection for COVID-19 testing and associated travel allowance under the PHE.

II. Office for Civil Rights

The Office for Civil Rights ("OCR") has issued notices of enforcement discretion regarding the application of Health Insurance Portability and Accountability Act ("HIPAA") regulations to telehealth services as well as disclosures by covered health care providers and business associates for public health and health oversight activities during the PHE. These measures have helped to ensure continued or enhanced patient access to essential health services that might not otherwise have been possible due to COVID-19 restrictions on in-person contacts. They also have helped facilitate sharing of critical data essential to pandemic response and management. While appropriate regulation of the security of telehealth and remote health services should be maintained, the data sharing policies reflected in these notices of enforcement discretion for HIPAA covered entities and business associates should inform a post-pandemic approach to the sharing of health data that would better support public health, even in the absence of a public health emergency.

A. Telehealth Remote Communications

OCR has provided notice that it will exercise its enforcement discretion and will not impose penalties for noncompliance with the regulatory requirements under the HIPAA Rules against covered health care providers in connection with the good faith provision of telehealth during the PHE. This is a meritorious policy during the PHE, to help ensure lower barriers to telehealth services and sustain patient care while observing various restrictions on in-person visits with health care providers. However, the security and privacy provisions of the HIPAA Rules are critical to ensuring protected communications with patients and instilling confidence in those who take advantage of telehealth services. This notice of

enforcement discretion should terminate concurrently with the PHE.

B. Uses and Disclosures of Protected Health Information

While the HIPAA Privacy Rule permits covered entities to disclose needed protected health information, without individual authorization, this does not extend to HIPAA business associates. OCR is exercising enforcement discretion and will not impose potential penalties for violations of certain provisions of the HIPAA Privacy Rule against covered health care providers or their business associates for uses and disclosures of protected health information by business associates for public health and health oversight activities during the PHE. Protected health information held by business associates may be critically important to public health activities, even outside of a PHE, and business associates may have greater data analytical capabilities than covered entities that could be brought to bear to support public health activities. OCR should consider maintaining this exercise of enforcement discretion indefinitely beyond the duration of the current PHE.

III. Expand Safe Harbor Modernizations to Enable Providers to Leverage Medtech Solutions

The COVID-19 pandemic highlights the need for our nation's health care system to better align care for patients and the great expense associated with providing that care in a disjointed manner. As part of its Regulatory Sprint to Coordinated Care, HHS published in the Federal Register final rules to modernize the regulations that interpret the federal Anti-Kickback Statute ("AKS"). These updates and revisions remove outdated barriers and facilitate value-based arrangements that would free innovation and foster a more coordinated response to patient care.

While medtech companies are on the front lines of care coordination and management, manufacturers of medical devices and durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) companies are not included in all new value-based safe harbors or the new outcomes-based payments safe harbors.

The medical technology industry plays a critical role in coordinating and managing care for patients. Through partnerships with care providers, medical technology provides data analytics, remote monitoring, and facilitates telehealth— areas that, during the PHE, have grown in use and become more important to drive care improvement. Including full participation in the value-based safe harbors by medical technology companies will greatly facilitate more innovative arrangements that can play a key role in care coordination while constraining costs.

As technology and innovation continue to evolve at unprecedented rates, we encourage HHS to promulgate full inclusion of medtech manufacturers in the new value-based framework to ensure all innovative value-based health care arrangements are protected and to advance beyond fragmented care to bring better solutions patients and provider need, which will improve health outcomes, reduce costs, and improve the patient experience.

IV. Food and Drug Administration

A. Devices Subject to Emergency Use Authorization or Enforcement Discretion

When the Secretary declared the PHE, the U.S. Food and Drug Administration ("FDA") was authorized to issue Emergency Use Authorizations ("EUA") for certain devices and device modifications. In addition, FDA has exercised enforcement discretion for other devices and device types throughout the PHE. As FDA considers how to transition devices subject to an EUA or enforcement discretion at the conclusion of the PHE, we provide below important issues for the Agency's considerations and our recommended solutions. These recommendations are intended to provide a smooth and efficient transition from EUA to marketing clearance or approval while ensuring that patients have access to safe and effective medical devices. The recommendations also provide for efficient clearance/approval of devices and device modifications subject to enforcement discretion as well as an efficient wind-down process for devices when an approval/clearance will not be sought. As stated above, consistent with the APA and 21 C.F.R. 10.115, we believe FDA should provide stakeholders reasonable notice and set out a transition plan with opportunity to comment prior to withdrawing or changing a COVID-19-related policy.

1. General Recommendations

FDA should establish processes for the smooth transition of devices subject to an EUA or enforcement discretion to clearance or approval. Our specific recommendations for this transition include:

- For high-volume product areas, reduce multiple pre-submission meetings with different manufacturers and ensure consistency of information and develop a standard template of information and data expectations for certain EUA devices seeking clearance or approval (*e.g.*, IVDs, ventilators). For IVDs, consider whether the EUA templates can be expanded to include a road map of expectations for 510(k)/*de novo* clearance.

- Allow submissions of relevant, reliable Real-World Data ("RWD") to support clearance or approval of the EUA or enforcement discretion device (or modification to a device).

FDA should issue the transition policy in writing with an opportunity for feedback and comment as soon as possible and well in advance of the end of the PHE. The transition should allow for a phased approach following the announcement of the end of the PHE. The transition policy should be risk-based and consider device type and benefits to patient safety and public health. In addition, the policy should consider whether the device is capital equipment or is intended for one-time use or reusable.

FDA should gradually transition certain regulatory requirements back into effect. The entire transition period should take approximately 12 months. The sequencing of policies should be:

- Medical device reporting ("MDR") and recall requirements should apply first, as applicable.

- Registration and listing requirements for those devices that do not currently have to comply per enforcement discretion should also apply first, when applicable.

- Premarket submission requirements: For those devices that would need clearance or approval and for which the manufacturer intends to continue marketing after the PHE concludes, the manufacturer should submit the application within 6 months after the PHE ends, or such longer period agreed upon by FDA. For those companies that submit by the deadline, FDA would enable continued marketing of the device while the submission is under FDA review.

- For those devices for which a manufacturer chooses not to seek clearance or approval within the 6-month timeframe, FDA would expect the marketing of the device to cease immediately at the end of the PHE.

- Generally, compliance with the Quality System and UDI requirements would be expected within the 12 months following the end of the PHE.

FDA should maintain policies and processes used during the PHE that worked well and continued to ensure safety and effectiveness of medical devices. For example, the policies specified within the following guidances should be maintained after the PHE concludes:

- *Conduct of Clinical Trials of Medical Products during the COVID-19 Public Health Emergency*;

- *Supplements for Approved Premarket Approval (PMA) or Humanitarian Device Exemption (HDE) Submissions During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency*;

- *FDA Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring During the Coronavirus Disease 2019*;

- *Policy for Diagnostic Tests for Coronavirus Disease-2019 During the Public Health Emergency (Revised)*;

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

- *Enforcement Policy for Imaging Systems During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency*;

- *Enforcement Policy for Digital Health Devices for Treating Psychiatric Disorders During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency*; and

- *Home-Use Blood Glucose Meters Used in Hospitals and Long-Term Care Facilities During the COVID-19 Pandemic*.

2. Devices/Capital Equipment Subject to an EUA

Below we provide our recommendations for devices/capital equipment currently on the market through an EUA and for which the manufacturer intends to seek clearance or approval but remains in distribution at the conclusion of the PHE.

- FDA should make the industry aware that a premarket submission should be submitted as soon as possible prior to, or no longer than, 6 months after the PHE concludes, to seek marketing clearance or approval for devices that are intended to continue to be used or marketed after the PHE.

- Any additional time required to submit a premarket submission (*e.g.*, due to collection of data to support submission) should be discussed on a case-by-case basis with the appropriate review division within the 6-month period after the PHE concludes.

- FDA should permit existing EUA products in the field to remain in the field when there is a pending premarket submission filed within 6 months of the start of the transition period.

- When an approval or clearance is received by the Agency, FDA should allow the EUA devices subject to approval or clearance to continue to be used and distributed during the review process if there have been no safety signals based on post market data.

- FDA should not require updates to labeling for the EUA devices while the review is pending. FDA should allow for reasonable labeling transition plans to account for printed labeling stock and labeled product. However, a manufacturer may choose to send updated labeling to EUA device customers if appropriate, or if required as part of the pending approval or clearance.

- FDA should allow EUA devices to be included under the new registration and listing information under the 510(k) for future post market activities (*e.g.*, complaint handling).

Below we provide our recommendations for devices/capital equipment currently on the market through an EUA and for which a manufacturer does not intend to seek clearance or approval but remains in distribution.

- If a premarket submission is not submitted within 6 months of the termination of the EUA, FDA should require the manufacturer to notify customers and health care

professionals of this fact (*i.e.*, explain that the products should no longer be used except in an another public health emergency, disclose any associated risk with continued use of the device, lack of serviceability, etc.).

- Manufacturers may send a customer notification informing them of the EUA termination and instructing them to stop using the device once the PHE concludes. Letters to customers should be sent within a reasonable timeline (6 months) after the PHE. There should be enforcement discretion for these devices during this timeframe.

- Manufacturers should be required to recover or retrieve physical devices.

- Manufacturers should not be responsible for service or maintenance of these devices after the PHE concludes.

    - If the device has an expiration date that is less than 3 months after the PHE, no action is needed.

    - If a manufacturer determines that it will retrieve the devices from the customer, there should be a reasonable timeframe after the PHE for the manufacturer to retrieve the device (*e.g.*, one year).

    - For devices that only included labeling changes to previously cleared devices (*e.g.*, indications for use and modified uses), manufacturers may send a customer notification informing the customer that the EUA for the device will terminate at the end of the PHE and instruct them that the device may continue to be used according to its cleared or approved labeling.

    - For devices that include EUA-related modifications to currently cleared or approved devices, those devices may continue to be used under enforcement discretion for the duration of the design-life of the capital equipment if their continued use poses a low safety risk.

3. Devices/Capital Equipment Subject to Enforcement Discretion

Below we provide our recommendations for modified devices currently on the market and for which the manufacturer intends to seek clearance/approval but remains in distribution.

- FDA should incentivize a premarket submission prior to the end of the PHE by establishing a streamlined process for enforcement discretion devices for which FDA policy determines clearance or approval is required after the PHE.

- FDA should exercise continued enforcement discretion for the modified uses of products pending premarket submissions that are filed within 6 months of the start of the transition period.

- A premarket submission should be submitted as soon as possible (within 6 months or within a time frame agreed upon with FDA, whichever is longer) after the PHE to seek clearance or approval for devices that are intended to remain in the market.

- When an approval or clearance is received, the devices subject to FDA's enforcement discretion that fall within the scope of that approval or clearance should be permitted to remain on the market.

- Devices subject to FDA's enforcement discretion that do not have a pending premarket submission within 6 months (or a timeframe agreed to by FDA, whichever is longer) after the PHE for the modified use should not be permitted to continue to be marketed or distributed.

- If a premarket submission is not submitted within 6 months (or a timeframe agreed to by FDA) after the PHE, the manufacturer must notify customers/HCPs that the modified uses for the products can no longer be used and the modified labeling must be disposed. This notification must occur within 6 months of the end of the PHE.

- For devices that include modifications to devices or modifications to the labeling that are currently cleared or approved, those devices may continue to be used for the duration of the design-life for capital equipment or until the expiration date for consumable equipment in accordance with modifications made under enforcement discretion if they pose a low risk for their continued use.

Below we provide our recommendations for modified devices for which the manufacturer does not intend to seek clearance/approval but remains in distribution after the PHE ends.

- If the product is a single-use device or has an expiration date that is less than 6 months after the PHE, no action is needed by the manufacturer and the product can remain on the market until its expiration date. Otherwise, the manufacturer should send a customer notification that: (1) informs the customer that the PHE has ended; and (2) either instructs the customer to stop using the device or provides modified labeling that has been cleared or approved by FDA. Letters to the customers should be sent within a reasonable time (6 months) after the PHE ends. FDA should exercise its enforcement discretion for these devices during the transition timeframe.

- Unless otherwise required by FDA for good cause, manufacturers should not be expected to recover or retrieve the modified device or its modified labeling.

- If the manufacturer chooses not to pursue clearance or approval of the modified use, manufacturers are not responsible for service or maintenance of the device for that modified use after sending the notification to the customer.

- For previously cleared or approved devices that only were subject to labeling changes (*e.g.*, indications for use or modified instructions for use), manufacturers must send a customer notification informing the customer that the modified labeling for the

device, per the relevant COVID-19 enforcement discretion guidance, will terminate within 6 months of the end of the PHE and instructing them that the device may continue to be used per its cleared or approved labeling.

- Previously cleared or approved devices that include modifications to the device or modifications to the labeling may continue to be used in accordance with the modifications made pursuant to FDA's enforcement discretion for the duration of the design-life for capital equipment or until the expiration date for consumable equipment, in accordance with the modifications made under FDA's enforcement discretion policy to the extent the device's continued use poses a low risk.

- If a manufacturer determines that it will retrieve the devices or the modified labeling from the customer, there should be a reasonable timeframe after the Emergency ends for the manufacturer to retrieve the device or modified labeling (a year time frame).

4. CLIA

For tests that FDA has determined qualifies for waived status through an EUA review, FDA should not repeat the assessment or require studies typically conducted as part of the CLIA waiver process if the same test is submitted for a subsequent premarket submission after the PHE ends for use in waived settings.

5. Clinical Trials

- Policies outlined in FDA's guidance, *Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergencies*, should continue after the PHE because they provide general considerations to assist sponsors to assure the safety of trial participants, maintain compliance with good clinical practice (GCP), and minimize risks to trial integrity. The following aspects of the guidance should be incorporated into future revisions of FDA's current clinical trial guidances:

    - Alternative Methods for Safety Assessments;

    - Alternative Secure Delivery of Certain Investigational Product;

    - Adaptation of Remote or Central Monitoring to Maintain Oversight of Clinical Trials; and

    - Alternative Methods for Informed Consent.

- FDA should consider the use of RWD collected for EUA devices or enforcement discretion devices in a premarket submission.

- FDA should provide a transition period of at least 6 months for studies underway that have incorporated the guidance into their study processes, procedures, or design to allow time to revise processes/procedures or to determine if the study can continue

under revised processes/procedures (*e.g.*, if a study was designed to take advantage of the COVID-19 guidance or an EUA/Enforcement Discretion device, it may need to be redesigned, re-approved, re-started, etc.).

6. Post Market Activities

- For complaint handling, we recommend a streamlined adverse event reporting option for devices that will not be transitioned to a cleared/approved device

- For facility inspections, we recommend FDA:

  - Continue to schedule routine facility inspections on risk/benefit decisions;

  - Conduct only "for cause" inspections of EUA device manufacturing facilities and devices under COVID-19 enforcement discretion guidances;

  - Conduct pre-approval inspections as applicable; and

  - Continue the MDSAP program.

B. COVID-19-Related Software Guidances

Below we provide our recommendations for how FDA can address issues related to the eventual transitioning of currently-in-effect guidance documents related to medical device software that were implemented as a result of the PHE, organized by guidance document.

1. Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (Revised)

Recommendation: After the PHE, FDA should not require regulatory submissions for modifications to the indications, claims, functionality, or hardware or software of non-invasive remote monitoring devices that support the inclusion of monitoring statements related to patients with COVID-19 and/or enable increased remote monitoring capability if the following conditions are met:

- The device is already 510(k)-cleared under the product codes provided in the guidance;

- The device manufacturer updates the device labeling in a manner consistent with the recommendations outlined in Section IV.A of the guidance; and

- The modification does not create undue risk (in a manner such as described in Section IV.A of the guidance).

If the modification is related to marketing the device in the home setting when it has only

been cleared for use in the hospital or healthcare setting, then the manufacturer should take the following actions:

- If the manufacturer intends to continue to market the product after the pandemic, the manufacturer should submit a 510(k) within 6 months after the PHE ends, or such longer period as agreed to by FDA. A phased approach to meet regulatory requirements should be consistent with other products. We appreciate FDA's willingness to consider data sources such as retrospectively collected RWD acquired during the PHE to expand the indications for use as described in the FDA guidance, *Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices*.

- If the manufacturer does not intend to continue to market the product after the PHE, the manufacturer should notify its customers within 6 months of the end of the PHE that the product should no longer be used in the home setting. During this time enforcement discretion for the device should continue to be exercised, and manufacturers should not be expected to retrieve or recover physical devices.

Recommendation: During and after the PHE, software functions intended to provide surveillance information regarding COVID-19 at a population level should be considered non-device software functions.

Rationale: For already commercially available devices that fall within the product codes provided in the guidance, most cleared indications for use are general such that they already include COVID-19 patient populations. For example, many breathing frequency monitors (product code BZQ) are cleared for use with adult, pediatric, and/or neonatal populations which includes COVID-19 patients. Further, there is no evidence that, for a given device type (such as a breathing frequency monitor), the risk profile for a specific indication for use in a COVID-19 population will be substantially different from that of the general indication for use. This is clearly described in FDA's guidance, *General/Specific Intended Use*, and such rationale contained therein should be applied in these instances. Therefore, device modifications to specifically market these products for patients with COVID-19 are not significant and do not require new 510(k)s.

Recommendation: For many hardware and/or software modifications that have been implemented to increase device remote monitoring capability, 510(k) submissions should not be required.

Rationale: Many functions that have been added to devices to improve their remote monitoring capabilities during the pandemic are non-device functions. For example, many devices have been modified so that they can be connected to a wireless network to transmit patient measurements directly to their healthcare provider. The addition of such hardware and software functionality to existing devices is specifically for the purpose of transferring and displaying information; it is not for interpreting the data generated. Such MDDS software functionality is exempt from the definition of device, per the 21st Century Cures Act, and the hardware is under enforcement discretion (as described in FDA's guidance,

Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices).

FDA should not require premarket review for modifications that incorporate such MDDS functionality, as long as manufacturers determine that the addition of the functionality does not introduce unmitigated risk that would result in significant harm, as described in FDA's guidance, *Deciding When to Submit a 510(k) for a Software Change to an Existing device*. This approach considers that the addition of a new non-device function is considered in a fashion consistent with a modification to a non-device function as described in Section VIII of FDA's guidance, *Multiple Function Device Products: Policy and Considerations*. Further, we believe the COVID-19 remote monitoring enforcement guidance suggests that new 510(k)s would be required for such MDDS-type modifications, and this is not accurate given the above rationale.

Recommendation: For devices that have previously been cleared only for use in hospital or healthcare settings but have been marketed for use in home settings during the pandemic, we believe RWD should be permitted to support regulatory decision making.

Rationale: During the PHE, the use of devices cleared for use in hospital or healthcare settings in home settings is yielding relevant and reliable RWD. As described in Section VI of the FDA guidance, *Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices*, because an IDE was not required for the use of the device in a home use setting, RWD is now being generated for uses outside of the device's cleared indications for use. Due to this unique scenario, the manufacturer should be allowed to design retrospective analyses to support an expansion of the indications for use.

Recommendation: FDA should not require regulatory submissions for modifications to existing remote monitoring devices or initial introduction of software functions that enable surveillance.

Rationale: In its *FAQs on Testing for SARS-COV-2*,[2] FDA defined surveillance activities for COVID-19 testing as "generally used to monitor for an occurrence, such as an infectious disease outbreak in a population or community, or to characterize the occurrence once detected." FDA has also stated that the Agency generally does not regulate surveillance testing. Such surveillance can also apply to remote monitoring software functions used to present deidentified yet relevant data (*e.g.*, temperature and respiratory rate) to non-HCPs for purposes such as tracing community spread of the virus. Although the enforcement policy for the remote monitoring guidance provides clarity for "non-device" clinical decision support functions that present results to health care professionals, sufficient guidance is lacking for surveillance use cases. We believe that with a sufficient update of the user interface and deidentification of data, surveillance information in which individual patient data is collected and presented as population data on remote monitoring devices would be outside of the definition of a medical device.

[2] *Available at* https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2.

Recommendation: For devices that have previously been cleared only for use in hospital or healthcare settings but have been marketed for use in home settings during the PHE, we believe a gradual transition to regulatory requirements should be carried out.

Rationale: The transition timelines recommended in this document are consistent with the timelines AdvaMed has previously proposed to the Agency in its *AdvaMed EUA/Enforcement Discretion Transition Recommendations* document.

2. *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*

Recommendation: We recommend the permanent adoption of policies not to require premarket notification for modifications made to prescription use fetal dopplers that lay users could be instructed to use in a home setting under the direction of a health care provider. These would include the following modifications:

- The fetal doppler is modified to incorporate software and/or hardware intended to facilitate remote access (*e.g.*, addition of wireless or Bluetooth capability).

- The fetal Doppler display is modified to facilitate understanding by a lay user and/or provide instruction to a lay user, including display of fetal heart rate (along with including required labeling specified by the FDA to ensure safe use).

Rationale: Ultrasound technologies enjoy a long history of safe and effective use. The limited modifications allowed above are, for the most part, already allowed to be made for diagnostic ultrasound systems regulated in the radiology space (*see, e.g.*, 21 C.F.R. 892.1550, 189.1560, and 892.1570 for Ultrasonic pulsed Doppler imaging system, Ultrasonic pulsed echo imaging system, and diagnostic ultrasonic transducer, respectively), which typically have much higher maximum acoustic output levels than fetal doppler devices. Therefore, a similar approach can be used to specify and implement safeguards for maximum allowable acoustic output levels, device use time, and others, under which these modifications can be made safely and effectively without prior premarket notification.

Recommendation: We recommend the permanent adoption of policies not to require premarket notification for modifications made to fetal and maternal monitoring devices that could be used by a heath care provider, by prescription, in a home setting. These would include the following modifications:

- Device modification to include software and/or hardware intended to facilitate remote access (*e.g.*, addition of wireless or Bluetooth capability).

- Hardware or software changes intended to make the device more mobile or facilitate transfer into and out of a transportation vehicle and into a patient's home (*e.g.*,

eliminate wired connection between transducer and monitor, changing the device interface to allow monitoring display and/or device controls on a table or mobile phone).

Rational: Ultrasound technologies enjoy a long history of safe and effective use. The limited modifications allowed above are, for the most part, already allowed to be made for diagnostic ultrasound systems regulated in the radiology space (*see, e.g.*, 21 C.F.R. 892.1550, 189.1560, and 892.1570 for Ultrasonic pulsed Doppler imaging system, Ultrasonic pulsed echo imaging system, and diagnostic ultrasonic transducer, respectively). The reason these modifications typically do not require premarket notification in radiology is because they are well understood modifications or represent functionality that already exists on another ultrasound system model that has been 510(k) cleared by the FDA. A similar approach should also be adopted for fetal and maternal monitoring devices, as described in FDA's final guidance, *Marketing Clearance of Diagnostic Ultrasound Systems and Transducers*. With adequate implementation and adherence of specified device safeguards, these modifications can be rapidly made in a safe and effective manner.

3. *Enforcement Policy for Digital Health Devices For Treating Psychiatric Disorders During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency*

Recommendation: We believe products that would typically require a 510(k) should submit an application for review, or otherwise withdraw the product from market. FDA oversight of a device's clinical validation is important to protect public health.

4. *Enforcement Policy for Imaging Systems During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency*

Recommendation: FDA should permanently adopt its enforcement policies not to require premarket notification for covered class II imaging devices. For class III devices, FDA should allow reporting of modifications to be completed through annual reports, consistent with the following:

- Modifications that expand mobility, portability, or relocation of medical imaging systems (*e.g.*, motors, batteries, electrical components, or other hardware and/or software modifications that enable conversion of fixed to mobile imaging systems; provide or increase the capability for wireless use or remote use; and, design changes intended to reduce electromagnetic emissions in confined spaces to prevent electromagnetic interference with surrounding systems).

- Modifications to protect the operator or patient (*e.g.*, addition of a barrier to protect the operator or patient from scatter radiation or provide additional protection against disease transmission).

- Design modifications to improve the ability to clean, disinfect, and/or sterilize the product.

Rational: For some imaging devices that do not require the use of a dedicated room (*i.e.*, FFDM, DBT, X-ray, ABUS, and Diagnostic Ultrasound Systems), modifications to add wheels, additional protective barriers to protect the operator and patient from scatter radiation, updated cleaning instructions, and converting the device from mains power to battery power are not likely to change the underlying device technology or intended use of the device. FDA has been allowing these types of modification and device alterations before the PHE. For example, modifications to allow mammography equipment to be retrofitted for mobile mammography services provided by van or bus are common to help with access to underserved communities and have not typically required additional clearance or approval. In this instance, the same principles apply if the modifications do not result in a change in diagnostic imaging quality or result in a significant difference in radiation exposure from scatter radiation.

Recommendation: FDA should permanently adopt its enforcement policies not to require premarket notification for Ultrasound Imaging Systems for the following modifications:

- Modifications to enable use of the ultrasound outside of its cleared environment of use (*e.g.*, in a temporary imaging situation with different or more variable environmental conditions, such as a general practitioner's office or a field hospital).

- Modifications to enable the collection of images by healthcare practitioners who are not trained in sonography under the guidance or supervision of a trained or licensed healthcare practitioner (*e.g.*, functionality to enable remote guidance).

Rational: Ultrasound devices are known for their safety, rapid real time imaging and extreme portability. The use of these devices by a trained professional has not typically been limited to a healthcare facility and they are commonly used in field hospitals, EMT vans, and a patient's home for concierge medicine. As long as the devices are in conformance with EMC testing for wireless immunity, there should be little to no concern with their safe and effective use by trained professionals.

We note, the use of remote guidance teleconferencing technology to allow an untrained healthcare practitioner to be guided or supervised by a trained or licensed sonographer may already be subject to FDA's enforcement discretion, or deemed not a device function, pursuant to the Agency's guidance, *Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act*, and further expanded upon in the guidance, *Policy for Device Software Functions and Mobile Medical Applications*. The decision to allow operation of an ultrasound device by an untrained healthcare professional under the supervision of a trained sonographer would be at the discretion of the hospital and physician (*i.e.*, a practice of medicine decision), allowable based on the relevant state's and/or

hospital's rules and regulations. Accordingly, we recommend permanent adoption of this policy or an explanation as to why such practice is not permissible.

Recommendation: FDA should permanently adopt its enforcement discretion policies not to require premarket notification for Image Analysis Software when adding additional capabilities for lung segmentation and measurements.

Rational: Currently, modifications to generally indicated anatomical segmentation software to add additional well-known anatomical structures (such as the lungs) do not typically require additional premarket notification before implementation. As such, we recommend that FDA permanently adopt this enforcement policy for modifications to add lung segmentation and measurements functionalities to Picture Archiving and Communications Systems (PACS) devices without requiring a 510(k) submission. We recommend that the Agency apply the same accuracy expectations and thresholds for the segmentation and measurement accuracies as is typical for these functions to ensure continued safe and effective use (*i.e.*, as long as segmentations and measurements are within ±20% of expected values a 510(k) is not needed for the modification).

Recommendation: FDA should issue guidance on performance data requirements to obtain FDA clearance or approval for modifications made as a result of this enforcement discretion guidance, including the addition of:

- A lung scanning clinical application (and/or lung scanning pre-sets) as identified for Ultrasound imaging systems in example #3.

- Image analysis tools that aid in the identification, evaluation, and monitoring of patients with non-specific findings associated with COVID-19, as identified for image analysis software in examples #2 and #3.

Rational: At the conclusion of the PHE, device manufacturers will need clear guidance on performance requirements and performance benchmarks needed to obtain FDA clearance or approval for device modifications released and implemented under FDA's COVID-19 enforcement discretion policy. Providing this guidance to device manufacturers will allow for a smoother transition and ensure health care facilities can continue to use and obtain these devices from device manufacturers that wish to continue marketing the newly added features.

5. *Enforcement Policy for Remote Ophthalmic Assessment and Monitoring Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency*

Recommendation: We recommend FDA follow the recommendations provided *infra*, Section II(A), concerning transition issues for devices subject to an EUA.

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

Recommendation: After the PHE, FDA should not require regulatory submissions for modifications and marketing claims that facilitate the use of digital pathology devices for remote viewing and reporting of digital pathology slides if the following conditions are met:

- The device is already 510(k)-cleared under product codes OEO, PSY, QKQ, and/or PZZ;

- The device manufacturer updates the device labeling with specific instructions for remote use, consistent with the content provided in Section IV.B. of the guidance; and

- The device manufacturer describes the display monitor specifications that must be followed by the end user. Rather than requiring digital pathology device manufacturers to claim a specific display monitor, FDA should allow device manufacturers to detail display monitor specifications that must be followed by end users.

If the device is a new digital pathology device intended for use in remote settings that has not been previously cleared under product codes OEO, PSY, QKQ, and/or PZZ, then the manufacturer should take the following actions:

- If the manufacturer intends to continue to market the product after the pandemic, the manufacturer should submit a 510(k) within 6 months after the public health emergency ends, or such longer period agreed to by FDA. For other regulatory requirements we recommend FDA follow the guidance AdvaMed provided in its EUA transition document

- If the manufacturer does not intend to continue to market the product after the PHE, the manufacturer should notify its customers within 6 months of the end of the PHE that the product should no longer be used. During this time enforcement discretion for the device should continue to be exercised and manufacturers should not be expected to retrieve or recover physical devices.

Recommendation: For a digital pathology device with an existing 510(k) clearance under product codes OEO, PSY, QKQ, and/or PZZ, we do not believe a modification that facilitates the use of the device for remote viewing warrants a new 510(k) submission.

Rationale: FDA has historically required device manufacturers to specify the display monitor that must be used for image viewing. Recent clearances (such as K201005 and K193054) illustrate this fact. Further, if a device manufacturer seeks to add a new display monitor to its device (such as moving from a Dell monitor to an HP monitor), such a change must undergo a new 510(k) review. End users are therefore limited to the type of display monitor they can use for reviewing their digital pathology images, and this also limits remote viewing opportunities.

Rather than focus on a specific display monitor type, we believe digital pathology device labeling should focus on display monitor specifications. This approach would broaden the display monitor options for end users and enable remote viewing while fulfilling device requirements and ensuring product safety and effectiveness. Further, this approach would clearly differentiate the device function (the digital pathology device) from the "other" function (the display monitor, often a consumer product and a non-device function). This type of differentiation is consistent with the multiple function approach described FDA's guidance, *Multiple Function Device Products: Policy and Considerations*.

Furthermore, FDA's guidance, *Deciding When to Submit a 510(k) for a Change to an Existing Device*, further suggests that FDA should not require a digital pathology device manufacturer to submit a new 510(k) for a change that facilitates remote viewing. Determining the significance of a device modification is predicated upon the risk imposed by that change, and FDA has acknowledged that hardware, software, and labeling changes to facilitate the remote use of digital pathology devices does not result in undue risk. Therefore, such changes should not be considered to have the potential to significantly affect device safety or effectiveness, and FDA should allow such changes to be implemented to existing devices without premarket review.

Additionally, it should be noted that end users of such digital pathology devices will still be required to fulfill applicable CLIA regulations and State laws, further ensuring that these devices will be used in a safe and effective manner and consistent with their product labeling.

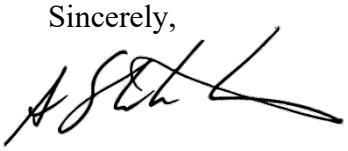
Recommendation: For digital pathology devices that have been marketed during the pandemic without existing 510(k) clearances under product codes OEO, PSY, QKQ, and/or PZZ, we believe a gradual transition to regulatory requirements should be carried out.

Rationale: The transition timelines recommended in this document are consistent with the timelines AdvaMed has previously proposed to the Agency in the document, *AdvaMed EUA/Enforcement Discretion Transition Recommendations*.

* * *

AdvaMed would like to thank HHS for its consideration of these comments. Should you have any questions, please contact AdvaMed's Chris White at cwhite@advamed.org, or Zach Rothstein at zrothstein@advamed.org.

Sincerely,



Scott Whitaker