AdvaMed
Advanced Medical Technology Association

May 12, 2025

By Electronic Submission to www.regulations.gov

Mr. Russell T. Vought
Director
Executive Office of the President
Office of Management and Budget
725 17th Street, NW
Washington, DC 20503

Re: Request for Information: Deregulation; OMB-2025-0003-0001

Dear Mr. Vought:

The Advanced Medical Technology Association ("AdvaMed") appreciates this opportunity to submit the below comments in response to the Executive Office of the President, Office of Management and Budget's ("OMB") Request for Information: Deregulation ("Deregulation RFI"), published at 90 Fed. Reg. 15,481 (April 11, 2025).

AdvaMed supports OMB's efforts to rescind or replace regulations that are unnecessary, unlawful, unduly burdensome, or unsound as doing so ensures medical technology companies can continue to successfully develop and manufacturer innovative and lifesaving/life-enhancing technologies that improve patient care and outcomes. We welcome the opportunity to assist OMB in its deregulation efforts and remain available to discuss further the recommendations included in these comments.

I. AdvaMed and the Medical Technology Industry's Role in Patient Health and Innovation

AdvaMed is a trade association that represents the world's leading innovators and manufacturers of medical devices, diagnostic products, digital health technologies, and health information systems. Together, our members develop and manufacture much of the lifesaving and life-enhancing healthcare technology transforming health care through earlier disease detection, less invasive procedures, and more effective treatments.

Our members, which range from the largest to the smallest medical technology innovators and companies, help patients stay healthier longer; recover more quickly after treatment; and enable clinicians to detect disease earlier and treat patients as effectively and efficiently as possible. At the same time, the innovation and advancements in medical technology driven by our members result in dramatically reduced healthcare costs.

The role of medical technology in improving patient health is well-known. In the U.S. there exists an innovation ecosystem for medical technologies that improve patient health and care. Indeed, the U.S. medical technology industry is responsible for a highly disproportionate share of medical advances globally.[1] Yet, this medical technology innovation ecosystem is fragile and extremely sensitive to changes in the cost of innovation, which is substantial.[2]

The fragility of the innovation ecosystem results from several factors, including the extremely expensive process from concept to product launch,[3] and numerous additional obstacles can stifle ideas and cost-saving improvements in healthcare from successfully reaching the market to help patients. In particular the complexity of the regulatory process and certain regulations that are unnecessary, unlawful, unduly burdensome, or unsound inhibit patient care and innovation, often impairing these efforts, and otherwise stifle American businesses and American ingenuity. The continued ability of medical technology companies to make rapid, significant, and sometimes transformational advances in healthcare technology depends upon a fair and reasonable regulatory system.

II. Regulations to be Rescinded or Replaced

We recommend and request that the following regulations[4] be rescinded or replaced as they fail to serve patient care and innovation, often impairing these efforts, and otherwise stifle American businesses and American ingenuity. These regulations are also unnecessary, unlawful, unduly burdensome, or unsound, as further discussed herein.

A. Laboratory Requirements

1. 42 CFR 493 - Laboratory Personnel Qualifications

We recommend rescinding the following changes to laboratory personnel qualifications as a result of the final rule issued by the Centers for Medicare & Medicaid Services ("CMS") and the Centers for Disease Control and Prevention (CDC) titled, "Clinical Laboratory Improvement Amendments of 1988 ("CLIA") Fees; Histocompatibility, Personnel, and Alternative Sanctions for Certificate of Waiver Laboratories" ("2023 CLIA Final Rule").[5]

(a) *42 CFR 493.1405(b) – Standard; Laboratory Director Qualifications.*

We recommend rescinding the changes to 42 CFR 493.1405(b) related to laboratory director educational requirements as a result of the 2023 CLIA Final Rule. Point-of-care ("POC") testing has become a standard of practice in many healthcare systems, allowing laboratory results to be delivered to the treating healthcare provider as rapidly as possible. The 2023 CLIA Final Rule significantly increased laboratory director educational requirements, without evidence of an issue.

Specifically, the modifications to the medical residency provision emphasizing the requirement for "clinical laboratory training" and requiring two years of experience supervising high complexity testing to

qualify for the position of laboratory director will reduce the number of medical doctors who qualify to function as laboratory directors for laboratories associated with their practice. This increase to educational requirements, combined with the existing decline in laboratory professionals, will lead to laboratory closures and impacts to patient diagnosis and care, especially in rural areas, and other areas experiencing health care deserts where physician office laboratories or laboratories in sites of emergency and critical care are owned and operated by the medical practice owner.

(b) *42 CFR 493.1411(b)(4)(i)(A) - Standard; Technical Consultant Qualifications.*

We recommend rescinding the changes to 42 CFR 493.1411(b)(4)(i)(A) related to laboratory technical consultant qualifications as a result of the 2023 CLIA Final Rule, which removed the nursing degree as a qualifying degree to operate as a technical consultant capable of documenting competency to run POC tests in moderately complex laboratories essential to critical care and emergency departments.

Medical doctor degree holders and bachelors of science in nursing should qualify similarly to bachelor's degree holders of chemical, biological, or clinical laboratory science, as was the case under the regulation before the 2023 CLIA Final Rule went into effect. No issues were identified with individuals holding a nursing degree to prompt the change in the regulation under the 2023 CLIA Final Rule and this change ultimately reduces the ability of nurses to perform this procedural role in testing. With an existing decline in laboratory professionals, reducing individuals with a bachelor of science in nursing from operating as a technical consultant reduces available professionals, which will lead to overburdened laboratories, which impacts the ability to deliver timely lab results and ultimately patient care.

(c) *42 CFR 493.1423(b)(7) – Blood Gas Analysis Testing Personnel Qualifications.*

We recommend rescinding the changes to 42 CFR 493.1423(b)(7) related to blood gas analysis testing personnel qualifications as a result of the 2023 CLIA Final Rule. The change of qualifications for blood gas testing under the 2023 CLIA Final Rule ignores standard test qualifications and implements higher education requirements in direct conflict with the preamble to the Final Rule and the qualifications of emergency medical technicians (EMTs) who perform these POC tests.

In the preamble to the 2023 CLIA Final Rule, CMS stated, "CLIA allows moderate complexity testing personnel to qualify with a high school diploma or equivalent and documented training of the testing performed prior to reporting patient test results. Individuals who meet the regulatory qualifications for moderate complexity can perform any test categorized by the U.S. Food and Drug Administration ("FDA") as moderate complexity, including blood gases."[6] Yet the regulations revised as a result of the Final Rule reflect a different, higher educational standard for blood gas testing. This requirement has a direct impact on the ability to deliver necessary and life-saving critical care enabled by blood gas testing. EMTs need to run blood gases during critical patient transport and many are no longer qualified under 42 CFR 493.1423(b)(7), as revised. Generally, to become an EMT, one needs a high school diploma or equivalent, CPR certification, completion of an EMT training program, and to pass the National Registry EMT exam and

a state-specific practical exam. A trained, competent, and experienced EMT, whose highest level of completed education is high school, should be allowed to run a blood gas test on a POC device. To not allow this will result in a negative impact on patient care.

2. 42 CFR 493.1804(c)(1) - Imposition of Alternative Sanctions.

We recommend rescinding the changes under the 2023 CLIA Final Rule that allow alternative sanctions to be levied against certificate of waiver ("CoW") bearing laboratories as unnecessary, unfair, impractical, and a detriment to access to care. The alternative sanctions are financial sanctions for CoW laboratories for improper proficiency testing referral. According to CMS, this change could decrease the burden for sanctions imposed, "[a]lthough we have no data indicating that principal sanctions have been imposed on CoW laboratories for this reason in the past."[7] In fact, proficiency testing is not a required process for laboratories only performing waived testing. This change creates new incentives for accrediting organizations to focus regulatory resources on monitoring compliance in waived laboratories, increasing their cost and burden of compliance for processes that are not currently being monitored today, without evidence of the need to do so. The increase in cost and burden for CoW laboratories will ultimately result in a reduction in their ability to provide necessary patient care. Furthermore, there are about 200,000 waived certificates, making effective oversight of this number of laboratories impractical.

3. 42 CFR 493, Subpart F – General Administration.

We recommend rescinding the changes to Subpart F of Title 42 related to CLIA fees under the 2023 CLIA Final Rule.

In December 2018, CMS increased fees to cover the cost of administering the CLIA program by 20 percent.[8] According to CMS, "The 2018 increase was intended to give CMS time to propose a process through rulemaking to allow for ongoing changes to the CLIA fees. Despite that increase, the level of carryover funding available to cover program expenses is projected to decline continuously. As such, the CLIA program will not be self supporting by the end of FY 2023 without an additional fee increase."[9] As a result, the 2023 CLIA Final Rule imposes an across-the-board fee update of 18%, and a change to allocate directly from CoW laboratories the cost for FDA to categorize clinical laboratory tests as waived, and modifies the CLIA fee provisions at Subpart F of Title 42. 89977. CMS claimed these changes would "stabilize the CLIA program."[10]

In fact, these changes will significantly increase the cost to operate laboratories, reducing laboratory viability, specifically in CoW laboratories. Furthermore, there is no evidence that these updates will "stabilize" the program financially, as the repeated increases in fees have not done so previously and only serve to exacerbate the existing consolidation of laboratories and shortages of laboratory professionals and services that impact access to care. Further increasing the bloat and cost of oversight with additional fee increases is not to the benefit innovation and access to care.

4. MLN Matters related to QW Modifier for CLIA-Waived Tests

We recommend rescinding the following Medicare Learning Network ("MLN") guidance documents related to CLIA-waived tests approved by the FDA:

- MLN Matters Number: MM13858, "New Waived Tests"[11]
- MLN Matters Number: MM13253, "New Waived Tests"[12]

These MLN Matters require that Medicare and Medicaid claims for certain laboratory tests categorized as waived under CLIA must have the modifier QW to be recognized as a waived test. This additional bureaucracy is unnecessary and causes delays in reporting usage (and reimbursement) of CLIA waived-tests on claim forms for laboratory tests that are already FDA-approved/cleared.

B. Medicare Reimbursement, Coverage, and Coding

1. 42 CFR § 405 Subpart B - Medicare Coverage Decisions for Health Care Technology

We recommend rescinding 42 CFR § 405 Subpart B related to Medicare coverage decisions for medical technology, including medical devices, and streamlining the process of reimbursement for FDA-approved Investigational Device Exemption ("IDE") studies.

The CMS approval process for Medicare reimbursement detailed in 42 CFR § 405 Subpart B contains many redundancies with the FDA approval process. Reimbursement for clinical trials requires both CMS coverage approval and establishment of coding. The process to establish coding can be prolonged and often occurs following coverage approval, contributing to delays in clinical trial access. Combining coding, coverage, and payment assignment into a single process, perhaps at the same time as FDA approval, would eliminate program administrative burden and improve timely trial access. We therefore recommend rescission of 42 CFR § 405 Subpart B and the introduction of a more appropriate streamlined process for these Medicare reimbursement decisions.

2. 42 CFR sections 412.87 and 412.88 - New Technology Add-On Payments

We recommend rescinding 42 CFR sections 412.87 and 412.88, or portions of the same, regarding additional payment for new medical services and technologies used in the inpatient setting as they relate to CMS' determinations of new medical services or technologies that are eligible for the new technology add-on payment ("NTAP"), and replacing the process detailed under these regulations with a quarterly review cycle of NTAP.

Under the current regulations, in order for a new medical service or technology to be eligible to receive the additional payment, known as NTAP, the medical service or technology must be new, costly, and demonstrate a substantial clinical improvement over existing services or technologies. CMS reviews NTAP applications and decides whether to award these payments on an annual basis. NTAP applications for a given fiscal year are due the October before that fiscal year ("FY") begins. As a general matter, applicants

for NTAP must receive FDA marketing authorization for their new medical service or technology by May 1 of the year prior to the beginning of the FY for which the application is being considered. § 412.87(f)(2). In addition, technologies must either be already FDA market authorized, or must have a complete and active FDA marketing authorization request at the time of NTAP application submission and must provide documentation of FDA acceptance or filing to CMS at the time of NTAP application submission, consistent with the type of FDA marketing authorization application the applicant has submitted to FDA. § 412.87(e).

These requirements are unnecessarily restrictive and significantly impact patient access and innovation. CMS currently requires documentation of FDA status and FDA marketing authorization on a timeline that is unrealistic, inconsistent with the FDA process, and burdensome for applicants seeking NTAP for innovative and necessary technologies. NTAP applicants are forced to manage great variables in the context of their FDA application process that would otherwise not be necessary but for CMS' NTAP review. Since CMS proposed this policy, industry and other public stakeholders have voiced numerous concerns regarding the fact that this regulation reflects a lack of understanding on CMS' part regarding the FDA process. CMS' timing requirements with respect to FDA documentation are inconsistent (way ahead) of expected FDA approval date. While CMS dismissed these public concerns in its decision to implement the policy, CMS has since had to revise its requirements twice through sub-regulatory guidance, in recognition of its flaws. Meanwhile, there have been at least six NTAP applications since 2023 that have been deemed by CMS "ineligible" for NTAP due to this flawed and arbitrary policy, resulting in at least a one-year delay of NTAP approval for these new medical services and technologies.

Limiting or delaying NTAPs for eligible medical services or technologies has significant patient access implications. Without NTAPs, facilities are unable to cover the incremental costs associated with new life-saving innovations, limiting access for patients who would benefit from these therapeutic options. In addition, this results in delayed uptake of critical life-saving technologies in the US, which have long been available in other parts of the world, impacting US health care innovative competitiveness. It also limits Medicare beneficiaries' access to innovative technologies, which is entirely inconsistent with CMS' strategic vision to "drive innovation to tackle our health system challenges."[13] Finally, the regulatory requirements reduce CMS's credibility as a thoughtful transparent government entity by repetitively denying proven flaws in a publicly critiqued policy.

The current NTAP process under the regulation is inconsistent with other analogous CMS programs and creates unnecessary burden in the inpatient setting. As an alternative to the current regulatory scheme, which is flawed as discussed above, we recommend that instead CMS establish a quarterly review cycle for NTAP, similar to the quarterly cycle used for applications for transitional pass-through ("TPT") status under the Medicare Hospital Outpatient Prospective Payment System ("OPPS"). The TPT process allows transparent, public review, but requires less administrative burden in rulemaking for CMS as compared to the NTAP process. Under this alternative process, like the TPT process, applications would still be submitted to CMS, but through a quarterly subregulatory process. The applications could be subject to notice and comment rulemaking in the next applicable Medicare Hospital Inpatient Prospective Payment System ("IPPS") annual rulemaking cycle. All applications that are preliminarily approved upon quarterly

review would automatically be included in the next applicable IPPS annual rulemaking cycle, while submitters of applications that are not approved upon quarterly review would have the option of being included in the next applicable IPPS annual rulemaking cycle or withdrawing their application from consideration. This process, in contrast to the current IPPS NTAP application and approval process would facilitate a more timely review of applications and would maximize appropriate NTAP approval for purposes of improving patient care and innovation.

3. 42 CFR § 419.66(b)(3) - Transitional Pass-Through (TPT) Payments for Medical Devices

We recommend rescinding 42 CFR §419.66(b)(3) related to transitional pass-through payments for medical devices and requiring that to be eligible a device must be an integral part of the service furnished, used for one patient only, come in contact with human tissue, and be surgically implanted or inserted or applied in or on a wound or other skin lesion.

The TPT program provides additional payments for new medical devices, drugs, and biologicals used in hospital outpatient settings under the OPPS. This program aims to facilitate access to these innovative technologies by incentivizing hospitals to adopt these innovations by covering the initial costs, while CMS gathers data to determine appropriate future payment rates. This, in turn, increases access to new technologies that might otherwise be too expensive for hospitals to adopt.

However, based on the current eligibility criteria at 42 CFR §419.66(b)(3), the program is significantly limited to only a minute subset of medical technologies. This criteria no longer reflects the current state of technology and should be removed. By limiting the TPT program to inserted or implanted devices, other technologies (such as clinical diagnostic tests) are unable to qualify for pass-through status and therefore face adoption challenges. Technologies currently ineligible are vital for patient care. The costs in terms of improving patient care and stifling innovation as a result of the current regulation far exceed any benefit to minimizing transitional pass-through payments. We therefore recommend rescinding 42 CFR §419.66(b)(3).

4. Prior Authorization

(a) *42 CFR 419, Subpart I - Outpatient Department Services*

We recommend rescinding 42 CFR 419, Subpart I related to prior authorization for outpatient department services. CMS cites section 1833(t)(2)(F) of the Social Security Act as authority for the regulations, which section allows the Secretary to develop "a method for controlling unnecessary increases in the volume of covered OPD services." However, CMS has failed to demonstrate that volume increases under OPPS were unnecessary. For example, Medicare claims data clearly demonstrates that the high growth rate of cervical fusions with disc removal in the hospital outpatient setting, cited in CY 2021 OPPS rulemaking as justification for prior authorization, was the direct result of services migrating from the more expensive hospital inpatient setting of care, and not due to medically unnecessary increases in overall utilization as the result of financial incentives, as CMS asserted. Requiring prior authorization for the service categories

listed at 42 CFR 419.83, including cervical fusion procedures, is bad policy, unreasoned, unsound, and represents an unjustified and significant burden to providers and patients. Needless administrative burdens, such as prior authorization requirements in these circumstances, negatively impacts patient care and innovation. Prior authorizations can also lead to confusion or delays in care for patients. As such, we recommend rescinding 42 CFR 419, Subpart I.

(b) *42 CFR 422.122 - Medicare Advantage Program*

We recommend rescinding 42 CFR 422.122, related to prior authorization requirements for Medicare Advantage Plans and all managed Medicare and Medicaid products, as the cost of these requirements outweigh any benefits and are unnecessary in light of technology advances. In addition, most denials from prior-authorization are later approved.

Prior authorization results in delays to patient care while increasing burden on providers, financial hardships, and higher costs. According to a 2022 report by the U.S. Department of Health and Human Services, Office of Inspector General ("OIG"), prior authorization can reduce access to care through the delay or denial of medically necessary medications and services.[14] Further, several studies suggest prior authorizations cost billions in dollars annually.[15] And according to a 2024 American Medical Association ("AMA") survey, prior authorization creates administrative roadblocks that frequently result in delayed care; increases costs for patients, caregivers, clinicians, and employers; and contributes to moral injury. In the AMA survey, nearly 25% of physicians report that prior authorization has led to a serious adverse event for a patient in their care.[16] The prior authorization regulation is also outdated and unnecessary. Prior authorization is still mostly a manual process, but technology can automate the process, making it nearly real-time.

5. National Correct Coding Initiative ("NCCI") Manual

(a) *Chapter 1: General Correct Coding Policies*

We recommend rescinding the following language in the NCCI Manual at Chapter 1, Section I:

> The American Medical Association [AMA] publishes *CPT Assistant*, which contains coding guidelines. CMS does not review or approve the information in this publication. As a result, CMS may adopt NCCI edits that are not consistent with *CPT Assistant*. If a physician uses information from *CPT Assistant* to report services rendered to Medicare patients, it is possible that MACs may use different criteria to process claims.[17]

This language causes confusion for coders and should be deleted. *CPT Assistant* is used by coders broadly. Any language that contradicts the guidance from the AMA/*CPT Assistant* makes it difficult for providers to determine appropriate coding. If NCCI edits are not clear and aligned with AMA *CPT Assistant*, it may be difficult for providers to properly order and perform services for patients. Coding errors impact patients and can lead to inaccurate or unnecessary cost-sharing estimates, prior authorizations, and other

delays in necessary care. As such, this language should be rescinded from the NCCI Manual, and approach discontinued.

(b) *Chapter 10: Introduction*

We recommend rescinding the following language in the NCCI Manual at Chapter 10, Section A:

> If a laboratory procedure produces multiple reportable test results, only a single HCPCS/CPT code shall be reported for the procedure. If there is no HCPCS/CPT code that describes the procedure, the laboratory shall report a miscellaneous or unlisted procedure code with a single unit of service.[18]

This language no longer reflects the current state of technology, creates unnecessary confusion, and prevents laboratories from reporting multiplex tests with existing CPT codes. Further, this requirement decreases patient access to multiplex covered tests that may not have a single multiplex code. Finally, uses of CPT codes, and how they relate to other CPT codes is already sufficiently addressed via NCCI edits themselves. As such, this language should be rescinded from the NCCI Manual, and approach discontinued.

(c) Chapter 10: Medically Unlikely Edits (MUE)

We recommend rescinding the following language in the NCCI Manual at Chapter 10, Section M.15:

> In the case of tests for infectious agents, methodologies include detection by immunofluorescence, immunoassay, or nucleic acid probe techniques. A single laboratory procedure shall be reported as one unit of service whether it generates one or multiple results. CPT codes that test for a single infectious agent that employ one procedure, one methodology, or one test kit are reported with one unit of service.
>
> CPT codes that test for multiple infectious agents are reported with one unit of service if one procedure, one methodology, or one test kit is used to perform the test (e.g., 87300, 87451, 87800, 87801). When multiple procedures, multiple methodologies, or multiple kits are medically necessary and used to perform a test for multiple infectious agents, the units of service reported for CPT codes that identify multiple infectious agents equals the number of different procedures, methodologies, or kits used to perform the test.
>
> For example, if a provider/supplier tests for 5 different species of an infectious agent using a single multiple-result test kit, only 1 unit of service for that test kit may be reported. However, if a provider/supplier tests for 3 different species of an infectious agent by using 3 different single result test kits, the provider/supplier may report 3 UOS of the appropriate CPT code.

This language contradicts the guidance from the AMA/*CPT Assistant,* which makes it difficult for providers to determine appropriate coding. Coding errors impact patients and can lead to inaccurate or unnecessary cost-sharing estimates, prior authorizations, and other delays in necessary care. As such, this language should be rescinded from the NCCI Manual, and approach discontinued.

6. National Coverage Determinations ("NCDs")

(a) *Breakthrough Technologies - TCET Pathway and MCIT Rule (42 CFR 405.601-405.607)*

We recommend rescinding the current method CMS uses to provide transitional coverage for emerging technologies ("TCET") through the national coverage determination ("NCD") process, and replacing it with the Medicare Coverage of Innovative Technology ("MCIT") rule previously finalized at 42 CFR 405.601-405.607.

Pursuant to a final rule published in early 2021, CMS established a Medicare coverage pathway to provide Medicare beneficiaries nationwide with faster access to new, innovative medical devices designated as breakthrough by the FDA (known as MCIT), to be detailed at 42 CFR 405.601-405.607. The MCIT rule would have granted expedited Medicare coverage for up to four years for any FDA-designated breakthrough device once the device received or cleared market authorization.[19] However, later that same year, CMS issued another final rule repealing the MCIT final rule.[20] Subsequently and as an alternative, in August 2024, CMS issued a final notice describing the method CMS would instead use to provide TCET through the NCD process.[21]

The TCET pathway, which uses current NCD and coverage with evidence development ("CED") processes to expedite Medicare coverage of certain FDA-designated breakthrough devices is costly and unnecessarily limits in the number of devices covered, thereby restricting patient access to life saving or life enhancing new technologies. In contrast, the MCIT rule, and regulations developed at 42 CFR Part 405.601-405.607, established an effective, expedited Medicare coverage pathway for recently authorized breakthrough designated medical devices. Devices and diagnostics that have been designated as breakthrough technologies have already completed rigorous FDA review and by definition meet currently unmet needs for patients with severe illness that have no, or limited, alternatives for treatment. Utilizing the slower TCET pathway, as opposed to the accelerated access available under the MCIT rule is unreasonable and represents bad patient care policy. We therefore recommend rescission of the TCET pathway and replacement with the MCIT rule, as finalized at 42 CFR 405.601-405.607.

(b) *NCD 40.2 - Blood Glucose Monitoring*

We recommend rescinding NCD 40.2 related to blood glucose monitoring.[22] This NCD restricts blood glucose monitoring to only people with diabetes. This restriction unnecessarily limits patient access to monitoring for necessary medical care. There are in fact other conditions besides diabetes that result in severe dysglycemic, and those patients could benefit from the use of continuous glucose monitoring. Examples include patients who are post-bariatric surgery and those who have certain diseases of the

pancreas. As a result, this NCD 40.2 should be rescinded and coverage decisions related to glucose monitoring left to the discretion of the Durable Medical Equipment ("DME") Medicare Administrative Contractors ("MACs").

C. 42 CFR 414.202 – Definition of Durable Medical Equipment

We recommend revising the definition of Durable Medical Equipment at 42 CFR 414.202 to remove the following two conditions:

- Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years; and
- Generally is not useful to an individual in the absence of an illness or injury.

The regulation as it currently exists is inconsistent with the underlying statute and no longer reflects the current state of technology. These current conditions are not required by statute and including them in the regulatory definition sets arbitrary limits on the types of technology that can be considered DME. This unnecessarily restricts new and innovative technology, particularly digital and AI-based technology, from the definition of DME. As such, we recommend revising the definition of DME at 42 CFR 414.202 as detailed above.

D. 42 CFR 403.904(c)(8)(ii) and 42 CFR 403.904(f)(1)(iv) - Open Payments Device Identifier Reporting Requirement

We recommend revising the Open Payments regulations at 42 CFR 403.904(c)(8)(ii) and 42 CFR 403.904(f)(1)(iv) to remove the requirement to report device identifiers ("DIs")[23] for general and research payments and transfers of value, respectively. This information does not provide meaningful information to the public and can create an inaccurate or misleading picture regarding the payments and transfers of value that are reported by manufacturers to CMS under the Physician Payment Sunshine Act. It also requires manufacturers to commit time, effort, and cost to maintaining systems and processes to collect and report this data, as opposed to focusing on medical technology innovation to improve patient care.

For additional context, many device manufacturers have tens of thousands, and some over one-hundred thousand DIs as individual products may be associated with multiple DIs because a different DI is required for each variation and version. For example, spinal fixation pedicle screws for degenerative disc disease could have a different DI for each variation in diameter, length, composition, coating, screw head and body connection (monoaxial, polyaxial, and uniplanar), thread depth, thread pitch, and version/model. Further, the pedicle screw is only one part of a spinal fixation system. Other components of a spinal fixation system include rods, rod connecters, plates, laminar hooks, and other types of connectors, where each component has different variations, and some variations have multiple versions, each of which requires a distinct DI. Interactions that involve a transfer of value related to a device frequently occur in the context of a product line or system, comprised of numerous individual devices that are components and options

within that product line or system. Reporting a multitude of DIs per product or system for a single payment record is onerous, may distort or confuse the circumstances of the interaction and associated transfer of value, and does not provide useful information to the public, as is the intent of the Open Payments Program. As such, we recommend rescinding 42 CFR 403.904(c)(8)(ii) and 42 CFR 403.904(f)(1)(iv).

E. Electronic Clinical Quality Measures

We recommend CMS rescind from quality reporting programs the Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults Electronic Clinical Quality Measure (the "eCQM"), including for the Hospital Inpatient Quality Reporting ("HIQR") Program, Hospital Outpatient Quality Reporting ("HOQR") Program, and the Merit-based Incentive Payment System ("MIPS").[24]

This eCQM is unnecessarily burdensome and based on unsound policy. The eCQM requires facilities to utilize a third party vendor software product to successfully report the measure data. Typically, eCQMs can be extracted from or directly reported within an electronic health record ("EHR") system regardless of the EHR vendor. However, eCQMs were not designed for radiology and cannot currently access and consume elements from Digital Imaging and Communications in Medicine ("DICOM") objects, so an additional resource is necessary for reporting the measure data. This has created operational challenges for facilities and clinicians and significantly increases the burden of reporting, which eCQMs are intended to reduce. Furthermore, the eCQM's technical specifications and limits for noise and dose compromise image quality and restrict clinicians from making appropriate and necessary adjustments to radiation doses, potentially resulting in inaccurate dosage or misdiagnosis. As such, we recommend CMS remove the eCQM from quality reporting programs.

F. FDA Regulations

1. **FDA should utilize the authority provided in Section 3054 of the 21st Century Cures Act (amending Sections 510(l) and 510(m) of the FDCA-see 21 U.S.C 360 (l) and (m) to exempt from the 510(k) requirement, using a streamlined mechanism, additional Class I and Class II devices that no longer warrant a 510(k).**

Section 3054 of the 21st Century Cures Act requires FDA to identify within certain timeframes and on a regular systematic cadence Class I and II devices currently subject to the 510(k) requirement that no longer warrant a 510(k), for instance the device is now well established and/or is better understood over time. These provisions provide for an efficient mechanism to exempt these lower risk devices from the 510(k) requirement. We encourage use of these exemption provisions, which provide for a risk-based, effective use of government regulatory resources and supports innovation for patients. We would be happy to assist with possible recommendations of devices for consideration.

2. FDA should utilize the authority provided in Section 707 of the FDA Reauthorization Act (FDARA) (FDARA)((adding section 513(f)(6) of the FDCA)) to distinctly classify accessories into class I.

The FDA has accessory classification authority under section 513(f)(6) of the FDCA, as amended by FDARA Section 707. In accordance with section 513(f)(6)(D)(i), the FDA finalized a list of accessories that the FDA found to be suitable for distinct classification in class I in 2019. In accordance with section 513(f)(6)(D)(i), the FDA is required to publish a list of accessories to be classified as class I at least once every 5 years. We encourage the FDA to meet its statutory requirements to publish a new class I accessories list.

3. Title 21, Chapter I – Point-of-Care (POC) Tests

We recommend FDA rescind the portion of those regulations that require manufacturers to submit a premarket notification to FDA for devices that are in vitro devices intended for POC testing, including 21 CFR § 878.9; 21 CFR § 882.9; 21 CFR § 862.9; 21 CFR § 864.9; 21 CFR § 874.9; 21 CFR § 866.9; 21 CFR § 880.9; 21 CFR § 884.9; 21 CFR § 868.9; 21 CFR § 872.9; 21 CFR § 888.9; 21 CFR § 870.9; 21 CFR § 876.9; 21 CFR § 886.9; 21 CFR § 890.9; 21 CFR § 892.9.[25]

The value of POC *in vitro* diagnostic testing, including those tests intended for use in a doctor's office, school, workplace or even the home, was demonstrated during the COVID-19 pandemic and continues to grow today. Significant regulatory hurdles make it extremely difficult for developers of POC tests to succeed. Throughout Title 21, identical limiting language appears requiring a test that would otherwise be low-risk—and could therefore be launched without FDA review— to go through FDA review for the sole reason that the test is intended for the POC setting. Identical limiting language appears repeatedly (e.g., 21 C.F.R. § 862.9(c)(9)). Over two decades have passed since the promulgation of these outdated regulations, and modernizing the treatment of near patient testing in a risk-based manner would benefit all patients. Categorically limiting a device simply because it is POC no longer makes sense. It does not support the public health in today's health care environment and it creates unnecessary regulatory hurdles that stifle innovation.

4. 21 CFR Part 11 - Electronic Records; Electronic Signatures

We recommend rescinding 21 CFR Part 11, related to the requirements for validation, audit trails, record retention, and electronic record copying. These requirements are currently subject to enforcement discretion per FDA guidance. This dates back to August 2003 when FDA announced that it was reevaluating Part 11 and exercising enforcement discretion for a narrower application of Part 11 while retaining the regulation in its entirety. The significant resource expenditures associated with Part 11 were identified as the reason for enforcement discretion. However, nearly twenty-two years later, Part 11 remains in the Code of Federal Regulations, even though they are outdated and unnecessary. These regulations set forth the criteria under which FDA considers electronic records to "be trustworthy,

reliable, and generally equivalent to paper records and handwritten signatures executed on paper."[26] Since the regulations were promulgated, the common use of electronic systems (and away from paper recordkeeping) has greatly expanded. We therefore recommend 21 CFR Part 11 be rescinded in its entirety (along with associated Part 11 guidance) in order ensure a modern and efficient regulatory framework.

5. FDA Guidance Documents

We recommend rescinding the following FDA guidance documents for the reasons discussed below with respect to each FDA guidance document.

(a) *510(k) Premarket Notification Draft Guidance Documents (2023)*

We recommend rescinding the following 510(k) draft guidance documents issued by the FDA in 2023 as they each include recommendations that are inconsistent with longstanding regulatory practice and they are not supported by existing statutes and regulations. We include directly below illustrative examples from each of these draft guidance documents to support our recommendations.

(1) *Best Practices for Selecting a Predicate Device to Support a Premarket Notification [510(k)] Submission: Draft Guidance for Industry and Food and Drug Administration Staff*[27]

This draft guidance document recommends manufacturers select a predicate device that meets certain characteristics to support a 510k premarket notice submission; however, there is no statutory basis to make or enforce such recommendation. The draft guidance document also recommends manufacturers disclose information regarding their predicate device selection process in a public-facing 510(k) summary; however, this information is not a required element per 21 CFR 807.92, it is irrelevant to the determination of a substantial equivalence determination, and may inadvertently result in disclosure of proprietary information.

(2) *Evidentiary Expectations for 510(k) Implant Devices: Draft Guidance for Industry and Food and Drug Administration Staff*[28]

This draft guidance document appears to change the definition of an implanted medical device as defined in 21 CFR 860.3(d). The draft guidance document also includes blanket recommendations that do not consider the risk of the device, which is inconsistent with FDA's longstanding benefit-risk and "least burdensome" principles.

(3) *Use of Clinical Data in Premarket Notification [510(k)] Submissions: Draft Guidance for Industry and Food and Drug Administration Staff*[29]

The examples and recommendations included in this draft guidance document related to the use of

clinical data in 510(k) submission suggest a deviation from the statutory standard to demonstrate equivalence and a shift towards a premarket approval ("PMA")-like demonstration of safety and effectiveness.

(b) *FDA Draft Guidance: Evaluation of Thermal Effects of Medical Devices that Produce Tissue Heating and/or Cooling: Draft Guidance for Industry and Food and Drug Administration Staff*[30]

We recommend rescinding this draft FDA guidance. It is overly broad in scope and will impede device discovery and developments. This guidance document widely applies to many device types and is well beyond the guidance it is intended to supersede. It includes within its scope all premarket submissions, including IDE applications—without any delineation across the product lifecycle. In addition, it is both inconsistent with the criteria for IDE applications and contrary to the least burdensome approach, in which Congress has directed the FDA take a least burdensome approach to medical device premarket evaluation in a manner that eliminates unnecessary burdens that may delay the marketing of beneficial new products.[31] Further, the guidance has created much confusion in light of its conflicts with FDA established policies and recognized standards and does not reflect a risk-based approach. As such, we recommend FDA withdraw this draft guidance and instead work with industry and other stakeholders to develop a workable tailored policy. Ideally, this would be done via established consensus standards development processes.

(c) *FDA Guidance: Notifying the Food and Drug Administration of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the Federal Food, Drug, and Cosmetic Act*[32]

We recommend FDA rescind this guidance and revise its approach to notice under Section 506J of the Federal Food, Drug, and Cosmetic ("FD&C") Act ("Section 506J") of discontinuance or interruption of device manufacturing in a public health emergency ("PHE"). This guidance revised previous guidance to expand the criteria and recommendations for reporting, inconsistent with Congress' focus on devices needed "during, or in advance of, a public health emergency." Further, pursuant to this guidance, FDA published an associated 506J Device List on its website[33] that is confusing and unnecessarily wide in scope. As an initial recommendation, FDA should withdraw the guidance and focus solely on Section 506J statutory reporting criteria and not "additional notifications." The expectation for expansive Section 506J reporting—referred to as "additional notifications"— beyond a PHE will further strain the supply chain while diverting already critical resources from vital manufacturing and response activities. While FDA may receive voluntary notifications pertaining to a permanent discontinuation or interruption in the manufacture of a device at any time, this concept should not be included in policy guidance for the industry.

Furthermore, FDA should revise its 506J Device List to focus on what is truly critical in a given or typical PHE consistent with Section 506J. Without a focus on key devices for which a positive impact on

availability can be made in a given PHE, we lose focus on what is truly critical for patients and healthcare providers. The above approach will result in a patient-centric approach tailored to maximize healthcare in a PHE and align with Congress' public health emergency focus and those devices that Congress prioritized in Section 506J.

Finally, before pursuing any expansion of requirements, outstanding challenges with the current system should be addressed. More transparency should be implemented around determinations of product shortages and public listing and delisting. Regulators are still absorbing how to interpret and understand the data it receives. With any additional reports, it is likely that regulators will not be able to keep pace with maintaining accurate, actionable data. It could also detract from efforts of medical technology manufacturers, who are supplying the products needed for PHEs and the routine practice of medicine while facilitating new innovations for U.S. patients.

(d) *FDA Guidance: Infusion Pumps Total Product Life Cycle*[34]

We recommend FDA rescind this guidance. This guidance was introduced in 2014 with an expectation that a safety assurance case ("SAC") would be submitted with all infusion pump 510(k) submissions. The SAC framework was intended to provide an organized case that the infusion pump adequately addresses hazards associated with its intended use within its environment of use. However, the SAC framework does not achieve its intended goal to improve safety, and it slows the submission and review of innovative devices.

(e) *FDA Cybersecurity Guidance Documents*

We recommend FDA rescind the following two guidance documents:

- *Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software*;[35] and
- *Information for Healthcare Organizations about FDA's "Guidance for Industry: Cybersecurity for Networked Medical Devices Containing Off-The-Shelf (OTS) Software"*.[36]

These guidance documents, issued in 2005, are dated, given the significant evolution of the cybersecurity landscape in the past two decades. Medical device cybersecurity has matured and evolved substantially, with more robust expectations through Section 524B of the FD&C Act, guidance, and industry best practices. Notably, FDA's Center for Devices and Radiological Health has already identified these guidance documents for review, revision, or withdrawal as part of its retrospective review process. In addition, there is terminology in these guidance documents that is no longer aligned with FDA's current cybersecurity guidance, potentially leading to confusion among stakeholders. Moreover, content in these guidance documents has largely been supplemented and replaced by FDA's more comprehensive premarket and postmarket cybersecurity guidance documents. Rescinding these guidance documents will help ensure that stakeholders are referencing up-to-date, relevant, and consistent cybersecurity expectations.

(f) *FDA Draft Guidance: Laser-Assisted In Situ Keratomileusis Lasers – Patient Labeling Recommendations*[37]

We recommend FDA rescind this draft guidance and engage in a collaborative effort to develop more appropriate patient labeling recommendations. The draft guidance is problematic in that its approach interferes with the patient-physician relationship, is not balanced, and fails to include both the benefits and risks of LASIK procedures.

(g) *FDA Guidance: Hydrogen Peroxide-Based Contact Lens Care Products: Consumer Labeling Recommendations – Premarket Notification (510(k)) Submissions*[38]

We recommend FDA rescind this guidance as outdated and unnecessary as the information included has been superseded.

(h) *FDA Guidance: User Labeling for Devices that Contain Natural Rubber (21 CFR 801.437); Small Entity Compliance Guide-Guidance for Industry*[39]

We recommend FDA rescind this guidance as outdated and unnecessary as the information included has been superseded.

(i) *FDA Guidance: Content and Format of Premarket Notification [510(k)] Submissions for Sharps Containers*[40]

We recommend FDA rescind this guidance as it contains outdated recommendations. There are recent ISO standards (ISO 23907-1 and-2)—both consensus standards recognized by FDA— that cover many of the same product safety and performance requirements included in the guidance document.

(j) *FDA Guidance: Commercially Distributed Analyte Specific Reagents (ASRs); Frequently Asked Questions*[41]

We recommend FDA rescind this guidance document as it interprets which products qualify as analyte specific reagents ("ASRs") inconsistent with (more narrowly than) the regulatory definition of ASRs at 21 CFR 864.4020(a).

(k) *FDA Guidance: Oncology Drug Products Used with Certain In Vitro Diagnostic Tests: Pilot Program*[42]

We recommend FDA rescind this guidance document. FDA did not provide an opportunity to comment prior to issuing the pilot as a final guidance, and thus it did not capture input on how to structure the pilot for success. To date, no one has enrolled in the pilot, and FDA officials have previously indicated that they are considering whether to continue the pilot. To the extent that FDA does continue the pilot, the guidance is not needed and should be rescinded.

G. EPA Regulations

1. EPA can boost efficiency and create regulatory certainty through enhanced interagency collaboration on medtech matters.

We welcome EPA's commitment to interagency collaboration and clear regulatory requirements. In that vein, we believe the Agency has the opportunity to increase efficiency and regulatory certainty for the medtech industry by coordinating pesticide regulatory activities with FDA. Currently, the agencies have overlapping responsibilities for certain medical devices and sterilants used to clean the devices. This has caused inefficiencies and confusion resulting in supply chain delays affecting access to critical health products for everyday Americans like ventilator filters, air purifiers and UV light devices, due to ad hoc delays and holds for redundant labeling obligations for products historically not regulated by EPA.

EPA can ensure a more cohesive and efficient regulatory framework by exercising its authority to eliminate these redundancies through the development of a Memorandum of Understanding (MOU) with FDA or alternatively opting to permanently exempt certain medtech products from EPA review altogether. The latter option would more permanently eliminate duplicative regulatory frameworks and enforcement threats through use of the authority given to the EPA administrator in § 25 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA); see 7 U.S.C § 136w(b). Congress anticipated this potential duplicative regulatory scenario and explicitly provided that "the administrator may exempt from the requirements [of FIFRA] by regulation any pesticide [or device] which the administrator determines … to be adequately regulated by another Federal Agency…" FIFRA § 25(b)(1). These actions would leverage the FDA's expertise in medical device regulation and create a more predictable environment for medtech manufacturers. By consolidating regulatory authority under FDA, the administration can foster innovation and ensure medical devices reach the market more swiftly, benefiting public health.

2. EPA should withdraw its late-breaking Update to *Recommendations of Specifications, Standards, and Ecolabels for Federal Purchasing*.[43]

The "Update" incorporated a newly proposed "healthcare" category broadly encompassing FDA-regulated medical devices and related medical supplies. It was swiftly finalized on December 4, 2024, without change or response to stakeholder comment.[44] At the onset, we reiterate our support for the goal to protect the environment and foster sustainable practices that reduce environmental impact. However, we find the recommendations infeasible and problematic for our national healthcare infrastructure, medical supply chain, and availability of critical medical technologies for U.S. patients.

Our products are rigorously regulated by FDA for safety and safety effectiveness, including our product labeling. Lumping our complex technologies with furniture, food service ware, or office supplies under unworkable standards does not serve procurement decisions to meet U.S. government healthcare needs. Medical technologies entail considerable research, development, and testing by U.S. medtech innovators with often years from concept to production and extensive safety standards must be met. We are concerned that these recommendations and infeasible standards promote unfounded concerns about the

safety and efficacy of FDA-regulated medical products. Looking ahead, we suggest working collaboratively with non-government stakeholders and relevant stakeholders, including U.S. FDA, Department of Defense, and Department of Veteran Affairs, on policies impacting device technologies to promote the public health and meaningful sustainable practices while advancing U.S. technological innovation

H. 37 CFR 201.40(b)(17) - DMCA Exemption

We recommend the Librarian of Congress ("Librarian") rescind 37 CFR 201.40(b)(17), related to an exemption from the prohibition against circumvention under the Digital Millennium Copyright Act ("DMCA")[45] for medical devices or systems to allow the diagnosis, maintenance, or repair of such devices or systems (the Exemption). Rescission of this regulation is critical for public health, patient safety, patient privacy, and protecting intellectual property. The regulation is also inconsistent with law and the DMCA was not properly applied in adopting the Exemption.[46]

Many medical devices are embedded with copyrighted software that enables functionalities of the device. These devices usually contain technological protection measures ("TPMs") to prevent unauthorized access to the copyrighted software, protecting the device from malicious code, among other patient safety-focused concerns. The anti-circumvention provision of the DMCA makes it illegal to circumvent a TPM used to prevent unauthorized access to copyrighted works, so the DMCA prohibits hackers from bypassing TPMs on medical devices enabled by copyrighted software. However, the statute also allows the Librarian to adopt temporary exemptions to this prohibition. The Librarian adopted 37 CFR 201.40(b)(17) to create an exemption to permit circumventing TPMs to access computer programs that are contained in and control the functioning of a medical device or system to repair, maintain, or diagnose problems with the medical device or system.

Of great concern, the Exemption creates serious safety risks for patients and promotes the violation of copyrights. It also negatively impacts medical technology innovation, health care costs, and supply chain integrity. It allows unauthorized, unregulated entities to hack into medical device software for repairs. These unauthorized, unregulated entities, known as independent service organizations ("ISOs"), are not obligated to adhere to FDA quality system regulation ("QSR") requirements. Of note, original equipment manufacturers (OEMs) contract with *authorized* ISOs to provide repair and maintenance services for OEM devices. In these approved instances, authorized access is provided by the OEM to the ISO, along with training, competency assessments, and validated parts and software to perform servicing that meets QSR requirements. Medical device software is broadly licensed and available to healthcare providers. TPMs do not restrict healthcare providers from using licensed clinical software on medical devices; they limit only what aspects of the software may be viewed, used, copied, and *modified*. In this way, TPMs provide critical protection to ensure the privacy of patient data and that appropriate users operate the proprietary OEM software.

Permitting an unauthorized, unregulated entity to circumvent protection measures to maintain, repair, or

modify a medical device without FDA oversight and without the manufacturer's consultation presents serious risks to patients and healthcare providers. The devices use advanced technologies that, if not employed according to well-researched and regulated safety standards, can introduce dangers to users, including electrical shock, mechanical failure, improper dosing, infection, and burns. In addition, improperly calibrated and maintained devices can severely harm or kill patients by overexposing them to ionizing radiation. Other improperly serviced devices, such as imaging contrast agent power injectors, can cause fatal air embolisms. In addition to these direct safety risks, failure to maintain or repair these devices properly could cause interference with other equipment, a delay in care, and misdiagnosis.

Further, the act of circumventing TPMs to access medical device operating systems and software applications creates cybersecurity vulnerabilities that risk the functionality of devices and the privacy of confidential patient health information stored on them. Whenever a software hack tool is used to access a device for diagnostic and maintenance purposes, the device is modified, potentially compromising the integrity of the software. This can produce unintended consequences. For example, it may introduce security vulnerabilities to the device and to any networks to which the device is connected. And it may interfere with the device's operability as intended. By permitting the circumvention of TPMs, the Exemption increases the cybersecurity risk of highly regulated and confidential patient data, and it puts the functionality of life-saving medical equipment in jeopardy, raising patient safety concerns.

Finally, permitting an unauthorized, unregulated entity to circumvent TPMs to maintain, repair, or modify a medical device without FDA oversight and without the manufacturer's consultation discourages manufacturer innovation by failing to protect their intellectual property.

For the foregoing reasons, we recommend the rescission of the DMCA exemption at 37 CFR 201.40(b)(17).

III. Conclusion

In order to ensure medical technology companies can continue bringing lifesaving/life-enhancing technologies to patients as quickly and effectively as possible, and to ensure patient health and innovation thrives in the U.S., reasonable regulatory reform is necessary consistent with our comments herein.

Thank you in advance for your consideration of AdvaMed's comments to the OMB's Deregulation RFI. Please do not hesitate to contact me with any questions at (202) 783-8700 or by email at cwhite@advamed.org.

Sincerely,
/s/
Christopher L. White
General Counsel & Chief Policy Officer
Advanced Medical Technology Association (AdvaMed)

ENDNOTES

[1] The United States is ranked first in various measures of healthcare innovation. *See, e.g.,* 2020 FREOPP World Index of Healthcare Innovation, ranking the United States first in Science & Technology Healthcare Innovation with a score of 75.14, well above second-place ranked Netherlands (49.97). Available at https://freopp.org/wihi2020-505b1b60bce6.

[2] See National Library of Medicine, National Center for Biotechnology Information, Public Health Effectiveness of the FDA 510(k) Clearance Process: Balancing Patient Safety and Innovation: Workshop Report at 21, available at https://nap.nationalacademies.org/download/12960 ("The medical device innovation ecosystem is fragile and extremely sensitive to changes in the cost of innovation, which is substantial. . . The system is already under immense economic pressure).

[3] Id.

[4] For purposes of these Comments, we interpret "regulation" broadly to mean, without limitation, regulations, rules, memoranda, administrative orders, guidance documents, policy statements, and interagency agreements, regardless of whether the same were enacted through the processes in the Administrative Procedure Act, which is consistent with the definition of this term in Executive Order 14192 of January 31, 2025 ("Unleashing Prosperity Through Deregulation").

[5] 88 FR 89976 (Dec. 28, 2023), *available at* https://www.federalregister.gov/d/2023-28170/p-417.

[6] Id.at 90013.

[7] Id. at 89980.

[8] 83 FR 67723 (Dec. 31, 2018), available at https://www.federalregister.gov/documents/2018/12/31/2018-28359/medicare-program-clinical-laboratory-improvement-amendments-of-1988-clia-fees.

[9] 88 FR 89976.

[10] Id.

[11] Available at https://www.cms.gov/files/document/mm13858-new-waived-tests.pdf

[12] Available at https://www.cms.gov/files/document/mm13253-new-waived-tests.pdf

[13] See blog, "My First 100 Days and Where We Go From Here: A Strategic Vision for CMS," by Chiquita Brooks-LaSure, Administrator, Centers for Medicare & Medicaid Services (Sep 09, 2021), available at https://www.cms.gov/blog/my-first-100-days-and-where-we-go-here-strategic-vision-cms

[14] OIG Report in Brief, OEI-09-18-00260, " Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care" (April 2022), available at https://oig.hhs.gov/documents/evaluation/3150/OEI-09-18-00260-Complete%20Report.pdf.

[15] See Robert Popovian and Wayne Winegarden, Health Science Journal, 2021, Vol. 15 No. 4: 833, "An Estimate of the Net Benefits from Prior Authorization Policies in the U.S.," available at https://www.itmedicalteam.pl/articles/an-estimate-of-the-net-benefits-from-prior-authorization-policies-in-the-us.pdf; Jeffrey Pfeffer et al, Academy of Management Discoveries, 2020, Vol. 6, No. 3, 1–16, "Magnitude and Effects of 'Sludge' in Benefits Administration: How Health Insurance Hassles Burden Workers and Cost Employees," available at https://jeffreypfeffer.com/wp-content/uploads/2020/10/AMD-Benefits-Pfeffer.pdf.

[16] 2024 AMA prior authorization physician survey, available at https://www.ama-assn.org/system/files/prior-authorization-survey.pdf.

[17] NCCI Manual, ch. 1, sec. I, available at https://www.cms.gov/medicare/coding-billing/national-correct-coding-initiative-ncci-edits/medicare-ncci-policy-manual

[18] *Id* at Ch. 10, sec. A.

[19] 86 FR 2987 (Jan. 14, 2021), https://www.federalregister.gov/documents/2021/01/14/2021-00707/medicare-program-medicare-coverage-of-innovative-technology-mcit-and-definition-of-reasonable-and.

[20] 86 FR 62944 (Nov. 15, 2021), federalregister.gov/d/2021-24916.

[21] 89 FR 65724 (Aug. 12, 2024), available at https://www.federalregister.gov/documents/2024/08/12/2024-17603/medicare-program-transitional-coverage-for-emerging-technologies.

[22]NCD 40.2, "Home Blood Glucose Monitors," available at https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=222

[23] The Device Identifier is the mandatory, fixed portion of a Unique Device Identifier that identifies the specific version or model of a device and the labeler of that device. 21 C.F.R. 801.3

[24] The eCQM was finalized for the HIQR Program, the HOQR Program, and MIPS at 88 FR 59154, 88 FR 81986, and 88 FR 79329, respectively.

[25] All of these regulation relate to limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act and include identical language (". . . manufacturers of any commercially distributed class I or II device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification to FDA before introducing or delivering for introduction into interstate commerce for commercial distribution the device when: . . . The device is an in vitro device that is intended: . . . For near patient testing (point of care).").

[26] 21 CFR § 11.1(a).

[27] U.S. Food & Drug Admin., Ctr. for Devices & Radiological Health & Ctr. for Biologics Evaluation & Research, *Best Practices for Selecting a Predicate Device to Support a Premarket Notification [510(k)] Submission: Draft Guidance for Industry and Food and Drug Administration Staff* (Sept. 7, 2023), https://www.fda.gov/media/171838/download.

[28] U.S. Food & Drug Admin., Ctr. for Devices & Radiological Health & Ctr. for Biologics Evaluation & Research, *Evidentiary Expectations for 510(k) Implant Devices: Draft Guidance for Industry and Food and Drug Administration Staff* (Sept. 7, 2023), https://www.fda.gov/media/171835/download.

[29] U.S. Food & Drug Admin., Ctr. for Devices & Radiological Health & Ctr. for Biologics Evaluation & Research, *Recommendations for the Use of Clinical Data in Premarket Notification [510(k)] Submissions: Draft Guidance for Industry and Food and Drug Administration Staff* (Sept. 7, 2023), https://www.fda.gov/media/171837/download.

[30] U.S. Food & Drug Admin., Ctr. for Devices & Radiological Health, *Evaluation of Thermal Effects of Medical Devices that Produce Tissue Heating and/or Cooling: Draft Guidance for Industry and Food and Drug Administration Staff* (Mar. 15, 2024), https://www.fda.gov/media/177004/download.

[31] See The Least Burdensome Provisions: Concept and Principles, Guidance for Industry and Food and Drug Administration Staff, issued February 5, 2019, *available at* https://www.fda.gov/media/73188/download.

[32] U.S. Food & Drug Admin., Ctr. for Devices & Radiological Health & Ctr. for Biologics Evaluation & Research, *Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act: Guidance for Industry and Food and Drug Administration Staff* (Jan. 7, 2025), https://www.fda.gov/media/155245/download.

[33] U.S. Food & Drug Admin., *506J Device List*, FDA (Jan. 6, 2025), https://www.fda.gov/medical-devices/medical-device-supply-chain-and-shortages/506j-device-list.

[34] U.S. Food & Drug Admin., Ctr. for Devices & Radiological Health, *Infusion Pumps Total Product Life Cycle: Guidance for Industry and FDA Staff* (Dec. 2, 2014), https://www.fda.gov/media/78369/download.

[35] U.S. Food & Drug Admin., Ctr. for Devices & Radiological Health, *Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software* (Jan. 2005), https://www.fda.gov/media/72154/download.

[36] U.S. Food & Drug Admin., Ctr. for Devices & Radiological Health, *Information for Healthcare Organizations about FDA's "Guidance for Industry: Cybersecurity for Networked Medical Devices Containing Off-The-Shelf (OTS) Software"* (Feb. 2005), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/information-healthcare-organizations-about-fdas-guidance-industry-cybersecurity-networked-medical.

[37] U.S. Food & Drug Admin., Ctr. for Devices & Radiological Health, *Laser-Assisted In Situ Keratomileusis (LASIK) Lasers – Patient Labeling Recommendations: Draft Guidance for Industry and Food and Drug Administration Staff* (July 28, 2022), https://www.fda.gov/media/160239/download.

[38]https://www.fda.gov/regulatory-information/search-fda-guidance-documents/hydrogen-peroxide-based-contact-lens-care-products-consumer-labeling-recommendations-premarket

[39] U.S. Food & Drug Admin., Ctr. for Devices & Radiological Health, *User Labeling for Devices that Contain Natural Rubber (21 CFR 801.437); Small Entity Compliance Guide; Guidance for Industry* (Apr. 1, 2003), https://www.fda.gov/media/71135/download.

[40] U.S. Food & Drug Admin., Ctr. for Devices & Radiological Health, *Guidance for Industry: Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software* (Jan. 2005), https://www.fda.gov/media/72328/download.

[41] U.S. Food & Drug Admin., Ctr. for Devices & Radiological Health & Ctr. for Biologics Evaluation & Research, *Commercially Distributed Analyte Specific Reagents (ASRs): Frequently Asked Questions: Guidance for Industry and FDA Staff* (Sept. 14, 2007), https://www.fda.gov/media/71127/download.

[42] U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Research, Ctr. for Devices & Radiological Health & Oncology Ctr. of Excellence, *Oncology Drug Products Used with Certain In Vitro Diagnostic Tests: Pilot Program: Guidance for Industry, Clinical Laboratories, and Food and Drug Administration Staff* (June 20, 2023), https://www.fda.gov/media/169616/download.

[43] U.S. Environmental Protection Agency, *Recommendations of Specifications, Standards, and Ecolabels for Federal Purchasing* (Jan. 23, 2025), https://www.epa.gov/greenerproducts/recommendations-specifications-standards-and-ecolabels-federal-purchasing.

[44] U.S. Environmental Protection Agency, *EPA Releases Final Updates to Recommendations to Help Buyers Find Sustainable Products* (Dec. 5, 2024), https://www.epa.gov/chemicals-under-tsca/epa-releases-final-updates-recommendations-help-buyers-find-sustainable.

[45] 17 U.S.C. 1201(a)(1)(A).

[46] See Memorandum of Points and Authorities in Support of Plaintiffs' Motion for Summary Judgment, Advanced Medical Technology Association, et al. vs. Library of Congress, et al., No. 1:22-cv-499 (BAH) (D.D.C.).