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Energy & Commerce Subcommittee on Health

On

"Innovation Saves Lives: Evaluating Medicare Coverage Pathways for Innovative Drugs, Medical Devices, and Technology."

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Chairman Guthrie, Ranking Member Eshoo, and distinguished members of the Subcommittee on Health:

My name is Brian Miller, and I practice hospital medicine at the Johns Hopkins Hospital. As an academic health policy researcher, I serve as an Assistant Professor of Medicine and Business (Courtesy) at the Johns Hopkins University School of Medicine. My research focuses on how we can build a more competitive and vibrant health sector to make healthcare more flexible and personalized for patients. This perspective is based upon my prior regulatory experience at the Federal Trade Commission, Federal Communications Commission, U.S. Food & Drug Administration, and the Centers for Medicare & Medicaid Services. Through my role as a faculty member, I regularly engage with regulators, policymakers, and businesses in search of solutions to help create a better healthcare system for all. Today I am here in my personal capacity, and the views expressed are my own and do not necessarily reflect those of the Johns Hopkins University, the American Enterprise Institute, or the Medicare Payment Advisory Commission.

In my testimony today, I will focus on:

1. Why we should care about fostering innovation
2. Current Medicare coverage policies and how to improve them
3. Improvements in medical device regulation to better support Medicare coverage
4. The need to think differently about paying for health technology

1. Why we should care about fostering innovation

As one of the most entrepreneurial countries in the world, we have made a choice to invest in the development of life-saving and life-changing technologies. Since 1950, the U.S. Food & Drug Administration (FDA) has approved over 1,200 new molecular entities (NME),[1] and in 2022 alone the FDA approved 22 NMEs and 15 new biologic drugs,[2] echoing a historical trend.[3] The medical device industry offers a similar story, with the FDA approving 22 new premarket approval (PMA) applications[4] and 3,194 510(k) clearances[5] in 2022. New paradigms continue to emerge, with the FDA having approved over 521 artificial intelligence/machine learning (AI/ML) devices as of the date of this hearing.[6]

This is not just a story of numbers, as innovation has resulted in meaningful improvements for both individual patients and populations. Life sciences innovation has driven changes in care delivery, with cardiovascular disease being a prime example. Innovation in surgical techniques and tools resulted in coronary artery bypass graft surgery becoming the standard of care for advanced cardiovascular disease. Subsequent innovation resulted in the rise of interventional cardiology and stenting, transforming a previously highly morbid surgical procedure into a far less morbid procedure. Pharmaceutical product innovation followed lockstep, with the development of new anti-platelet agents to prevent cardiac in-stent thrombosis, statins to lower cholesterol, improved blood pressure medications such as angiotensin receptor blockers, and recently the development of fixed-dose, combination products such as sacubitril/valsartan to treat advanced heart failure.

Advances in life sciences innovation have supported the epidemiologic transition,[7] wherein our country's innovation focus has moved from anchoring on treating infectious disease to chronic conditions. In particular, innovation has driven a transformation of what historically was a death sentence into a chronic disease–be it antiretroviral therapy for

[1] Munos, B. Lessons from 60 years of pharmaceutical innovation. *Nat Rev Drug Discov* 8, 959–968 (2009). https://doi.org/10.1038/nrd2961
[2] U.S. Food & Drug Administration. CY 2022 CDER New Molecular Entity (NME) Drug & Original BLA Calendar Year Approvals. (2022). https://www.fda.gov/media/165828/download
[3] U.S. Food & Drug Administration. Summary of NDA Approvals & Receipts, 1938 to the present. (2018). https://www.fda.gov/about-fda/histories-product-regulation/summary-nda-approvals-receipts-1938-present
[4] U.S. Food & Drug Administration. Devices Approved in 2022. (2023). https://www.fda.gov/medical-devices/pma-approvals/devices-approved-2022
[5] U.S. Food & Drug Administration. 510(k) Devices Cleared in 2022. (2023). https://www.fda.gov/medical-devices/510k-clearances/510k-devices-cleared-2022
[6] U.S. Food & Drug Administration. Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices. (2022). https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-aiml-enabled-medical-devices
[7] McKeown RE. The Epidemiologic Transition: Changing Patterns of Mortality and Population Dynamics. *Am J Lifestyle Med*. 2009;3(1 Suppl):19S-26S. doi:10.1177/1559827609335350

the treatment of the Human Immunodeficiency Virus (HIV). With what could have been just weeks to months between diagnosis and death prior to the development of antiretroviral treatments, we now see life expectancy extended by 35 to almost 40 years;[8] or the case of metastatic melanoma, with the emergence of PD-1 inhibitors such as pembrolizumab or a combination of nivolumab and ipilimumab innovation has transformed a virtual death sentence and extended survival for 6 years or longer.[9] Fostering this transition for other diseases and providing Americans a new lease on life is a worthy societal investment.

Health care service delivery unfortunately faces unique challenges and offers a platform for improvements through the application of new technology, automation, and AI. While consolidation and monopoly power are undoubtedly significant drivers of flat hospital labor productivity from 1993-2020,[10] technology and, in particular, artificial intelligence offer the positive potential of improvement through 1) "automation of the mundane" (administrative tasks), 2) augmenting existing clinical labor, and 3) eventual independent autonomous treatment. While a Star Trek world of medical care is still a ways off, coupling telehealth and carefully considering new ways to pay for medical devices and new technology can democratize access to mass-produced, mass-customized care in a modality, time and place best suited to an individual beneficiary's needs.

2. Current Medicare coverage policies and how to improve them

Technology assessment and coverage analysis is a core health plan function, a function made more critical as public health benefits program use taxpayer funds to support coverage of items and services. There are six primary reasons to finance a medical service or product: prevention, screening, diagnosis, treatment, rehabilitation, and palliation. As part of technological assessment, health plans must consider technical properties such as manufacturing and reliability,[11] along with more traditional considerations such as safety and efficacy (and/or effectiveness). Historically, public payers have been unable to consider economic performance in coverage decisions, something that private payers have used extensively. Finally, even though not part of a statutory mandate, public and private payers carefully consider social, legal, ethical, and political impacts of coverage decisions. The Medicare program is no exception.

Centers for Medicare & Medicaid Service (CMS) staff have a litany of choices, including the initiation of a national coverage determination (NCD), deferring to Medicare area contractors (MACs) and thus promoting local coverage determinations (LCD), or coverage with evidence development (CED). There are also various flavors of the aforementioned options, e.g. an NCD with restrictions to certain patient populations, physician specialties, or facilities. Coverage may also change over time, with evidence generation during CED leading to a subsequent NCD, or a removal of restrictions on a narrower NCD.

[8] Trickey A, Sabin CA, Burkholder G, et al. Life expectancy after 2015 of adults with HIV on long-term antiretroviral therapy in Europe and North America: a collaborative analysis of cohort studies. *Lancet HIV*. 2023;10(5):e295-e307. doi:10.1016/S2352-3018(23)00028-0

[9] Wolchok JD, Chiarion-Sileni V, Gonzalez R, et al. Long-Term Outcomes With Nivolumab Plus Ipilimumab or Nivolumab Alone Versus Ipilimumab in Patients With Advanced Melanoma. *J Clin Oncol*. 2022;40(2):127-137. doi:10.1200/JCO.21.02229

[10] U.S. Bureau of Labor Statistics. Private Community Hospitals Labor Productivity. https://www.bls.gov/productivity/highlights/hospitals-labor-productivity.htm

[11] The Pfizer COVID-19 example is the quintessential example of the need for careful consideration of technical properties: it originally required transport at -70° C. Simmons-Duffin, S. "Why Does Pfizer's COVID-19 Vaccine Need to be Kept Colder Than Antactica?" *NPR*. (2020). https://www.npr.org/sections/health-shots/2020/11/17/935563377/why-does-pfizers-covid-19-vaccine-need-to-be-kept-colder-than-antarctica

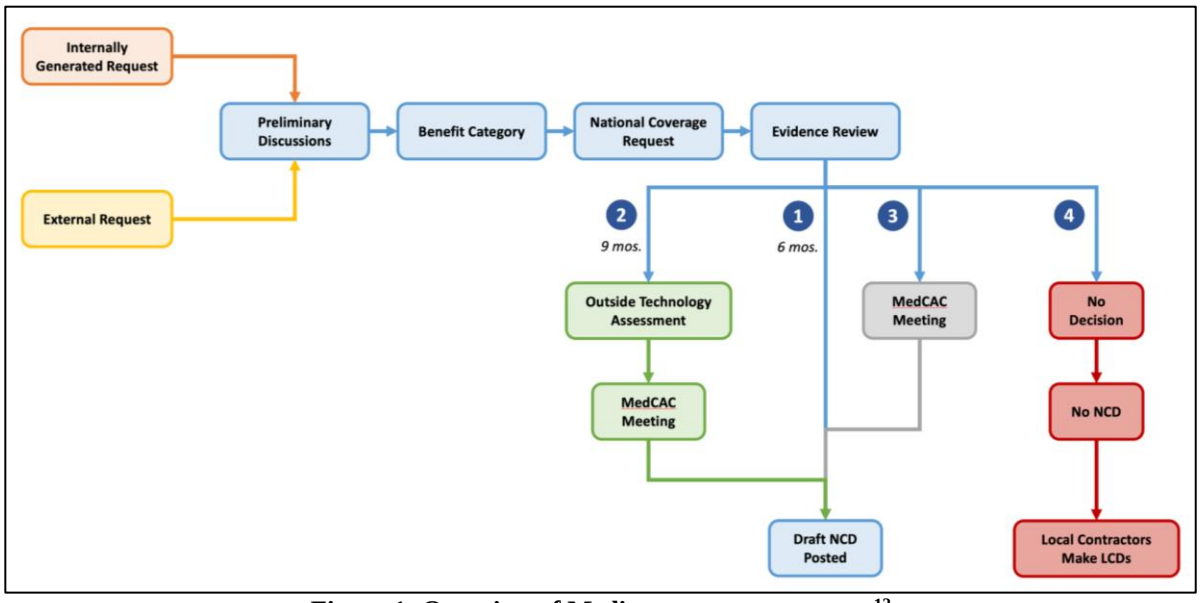

Figure 1: Overview of Medicare coverage process[12]

Outcomes considered include effects on morbidity, mortality, disease occurrence, adverse events from therapy/service, functional status, and quality of life. For the Medicare program, Congress determines the benefit category, the FDA approves or clears drugs and devices for the marketplace, and CMS may cover over label uses. In order to be covered by the Medicare program, an item or service must be legal, have a benefit category and code, and be "reasonable and necessary."[13] CMS has attempted to assist industry through guidance regarding the coverage process, with a 2013 *Federal Register* notice[14] providing an overview of the coverage process.

Process has historically been a challenge. In 1999, under the leadership of Administrator Nancy-Ann DeParle and the Clinton Administration, the then Health Care Financing Administration (now CMS) overhauled the coverage and analysis group (CAG) at CMS,[15] increasing staff, transparency, and improving processes including setting up the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC)–an external independent advisory body of which I am a former member. The subsequent years noted a vibrancy of coverage decisions and flourishing use of regulatory tools, with 6 meetings in the calendar year 2000 alone. In contrast, over the past 10 years, the MEDCAC has met 14 times.[16] NCDs have been similarly declining prior to the pandemic, with 2 completed in both 2018 and 2019 and 8 completed in 2020 (four of which were for acupuncture services),[17] with primarily updates to prior NCDs completed during the pandemic.

It is in this vein that beneficiaries, clinicians, and entrepreneurs are increasingly frustrated. In order to provide access to new items and services to Medicare beneficiaries, certainty of process is required with timelines, transparency, public input, and guidelines as to when certain pathways are used. In January of 2021, the Trump Administration released the Medicare Coverage of Innovative Technology (MCIT) rule,[18] providing breakthrough devices with four years of guaranteed coverage and eliminating the need for entities seeking coverage from multiple MACs. The

[12] Caveney B & Miller BJ. Technology Assessment & Coverage Analysis. (March 2023). Lecture, University of North Carolina, Chapel Hill. 2023
[13] Social Security Act, Section 1862(a)(1)(A-B)
[14] Centers for Medicare & Medicaid Services. Medicare Program; Revised Process for Making National Coverage Determinations. *Federal Register* 2013;78(152):48164-48169. https://www.govinfo.gov/content/pkg/FR-2013-08-07/pdf/2013-19060.pdf
[15] Responding to Plans, Providers, HCFA Expected to Go Slow on Risk Adjustment. (1999). *Inside HCFA*, 2(1), 1–7. http://www.jstor.org/stable/26685195
[16] Centers for Medicare & Medicaid Services. National Coverage MEDCAC Meetings Report Results. https://www.cms.gov/medicare-coverage-database/reports/national-coverage-medcac-meetings-report.aspx?year=all#
[17] Centers for Medicare & Medicaid Services. National Coverage MEDCAC Meetings Report Results. https://www.cms.gov/medicare-coverage-database/reports/national-coverage-annual-report.aspx?docType=NCD&year=2021&sortBy=title
[18] Centers for Medicare & Medicaid Services. "CMS unleashes innovation to ensure our nation's seniors have access to the latest advancements." (2021). https://www.cms.gov/newsroom/press-releases/cms-unleashes-innovation-ensure-our-nations-seniors-have-access-latest-advancements

proposed rule also would have codified the definition of "reasonable and necessary."[19] However, this rule was subsequently repealed by the Biden Administration,[20] and the agency spent 18 months working on a recently released alternative, the Transitional Coverage for Emerging Technologies (TCET) pathway.[21] Simultaneously, CMS released updated CED guidance[22] along with National Coverage Analysis Evidence Review guidance.[23]

Functionally, TCET is a an applied-for pathway (rather than a guarantee as MCIT was) for breakthrough devices. If accepted, a device undergoes an evidence preview, NCD, and, if needed, evidence development plan. This is followed by an anticipated 3-5 years of CED, with a subsequent NCD reconsideration at the end of the TCET period. This is a voluntary program subject to CMS discretion, and the agency notes that it anticipates being able to support five devices through TCET annually[24]–just a tiny fraction (or 3%) of the 166 breakthrough device designations granted in 2022[25] (noting that not even all of those will receive marketing authorization).

While TCET is functionally a small step in the right direction as it provides an alternative channel and a guarantee for CED for a small number of devices, it is a band aid applied to a dysfunctional and broken technology assessment process at CMS. CMS should be subject to binding timelines, transparency, regular opportunity for public input, and be required to issue and regularly update guidelines for when it uses which coverage tools. For example, CMS should be required to publish and regularly update guidelines by which it commissions an external technical assessment, convenes the MEDCAC, or defers coverage decisions to MACs. The atrophy of technical assessment and coverage analysis seen prior to and during the COVID-19 pandemic not only means that beneficiaries may be denied access to new and innovative services, but also that they may be getting services that they do not need or are in fact harmful. An often unmentioned function of a coverage analysis group is the reconsideration of prior coverage decisions.

While "reasonable and necessary" is considered to be a challenge to define, this can and should be defined in rulemaking in order to provide a clear barrier or path to coverage and payment for new technologies and services. An administrative definition is not set in stone: the definition of "reasonable and necessary" can be adjusted over time as appropriate in response to market shifts.

Pharmaceutical product coverage is another area of recent controversy, with the now 30-year old accelerated approval pathway a target of some policy experts.[26,27] An important market entry mechanism, accelerated approval permits early market entry for drugs that treat serious conditions, fill an unmet medical need, and are approved on a surrogate endpoint, to be confirmed in a trial as part of a post-market requirement (PMR). Originally a pathway by which antiretroviral therapies were approved for HIV,[28] the accelerated approval pathway is now a critical route to market for products treating hematologic malignancies and advanced cancer, with FDA approving 53 new molecular entities

[19] Centers for Medicare & Medicaid Services. Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary." *Federal Register* 2021;86(9):2987-3010. https://www.govinfo.gov/content/pkg/FR-2021-01-14/pdf/2021-00707.pdf
[20] Centers for Medicare & Medicaid Services. CMS Repeals MCIT/R&N Rule; Will Consider Other Coverage Pathways to Enhance Access to Innovative Medical Devices. (2021). https://www.cms.gov/newsroom/press-releases/cms-repeals-mcitrn-rule-will-consider-other-coverage-pathways-enhance-access-innovative-medical
[21] Fleisher L, Farmer S, Ashby L, & Blum J. "Transforming Medicare Coverage: A New Medicare Coverage Pathway for Emerging Technologies and Revamped Evidence Development Framework." (2023). https://www.cms.gov/blog/transforming-medicare-coverage-new-medicare-coverage-pathway-emerging-technologies-and-revamped
[22] Centers for Medicare & Medicaid Services. (PROPOSED) Coverage with Evidence Development. (2023). https://www.cms.gov/medicare-coverage-database/view/medicare-coverage-document.aspx?mcdid=35&docTypeId=1&sortBy=title&bc=16
[23] Centers for Medicare & Medicaid Services. (PROPOSED) CMS National Coverage Analysis Evidence Review. https://www.cms.gov/medicare-coverage-database/view/medicare-coverage-document.aspx?mcdid=34&docTypeId=1&sortBy=title&bc=16
[24] Centers for Medicare & Medicaid Services. Medicare Program; Transitional Coverage for Emerging Technologies. *Federal Register* 2023;88(122):41633-41644. https://www.govinfo.gov/content/pkg/FR-2023-06-27/pdf/2023-13544.pdf
[25] U.S. Food & Drug Administration. Breakthrough Devices Program. (2023). https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program
[26] Rome BN, Feldman WB, Kesselheim AS. Medicare Spending on Drugs With Accelerated Approval, 2015-2019. *JAMA Health Forum*. 2021;2(12):e213937. doi:10.1001/jamahealthforum.2021.3937
[27] Gyawali B, Ross JS, Kesselheim AS. Fulfilling the Mandate of the US Food and Drug Administration's Accelerated Approval Pathway: The Need for Reforms. *JAMA Intern Med*. 2021;181(10):1275-1276. doi:10.1001/jamainternmed.2021.4604
[28] National Organization for Rare Disorders. FDA's Accelerated Approval Pathway: A Rare Disease Perspective. https://rarediseases.org/wp-content/uploads/2021/06/NRD-2182-Policy-Report_Accelerated-Approval_FNL.pdf

and over 93 indications over the past 25 years.[29] It is important to note that accelerated approval is not conditional approval, as reviews maintain rigorous standards.[30]

Policy proposals to change how plans evaluate, cover, and pay for these drugs should be subject to a high standard, noting that changes risk disrupting 30 years of precedent in expanding early access to innovation. Products approved through expedited review offer greater gains,[31] and the FDA works hard to address so-called dangling approvals that lack PMR completion.[32] While some experts have noted concerns regarding the failure of completion of PMRs, confirmatory trials are frequently delayed for a variety of reasons including difficulty with enrollment, excessive clinical trial documentation, regulatory burden, etc. This is best addressed through improvements in the FDA regulatory process, and more importantly, in reducing the burdens of clinical trial design execution through the promotion of the use of real world evidence and the movement of clinical trials into a community setting. Coverage and payment policy should not be used to punish product developers for unavoidable operational challenges in the product development lifecycle or to hold small biologics companies responsible for the regulatory challenges of running clinical trials for drug development.[33]

In summary, in order to improve coverage for items and services–including medical devices and technology–CMS needs additional structure and guidance from Congress to recapture its positive and active role in technology assessment and coverage analysis.

3. Improvements in medical device regulation to better support Medicare coverage

A discussion of technology assessment and coverage would be incomplete without addressing ways to better support evidence generation for and review of medical devices. The FDA's Center for Devices and Radiological Health (CDRH) oversees devices that are meant to diagnose, cure, mitigate, treat, or prevent disease. Devices comprise everything from surgical knee replacements to stethoscopes. The FDA operates under a risk-based regulatory system created by the 1976 Medical Device Amendments and subsequently revised over time.

Class I or low risk devices such as bandages and wheelchairs are subject to general controls such as good manufacturing practices, device registration and listing and other regulatory tools. Class II or moderate-risk devices such as magnetic resonance imaging scanners or intravenous medication infusion pumps require pre-market notification and specific controls e.g. post-market surveillance, meeting FDA-recognized performance standards, etc. Class III or high-risk devices such as pacemakers require a pre-market approval (PMA) application including the submission of clinical trials to support the assurance that a medical device is safe and effective. Devices marketed after the 1976 amendments are considered class III and require submission and approval of a PMA, unless the manufacturer can demonstrate that a class I or II device is substantially equivalent to a previously marketed device. If so, the manufacturer can then file a 510(k) submission and seek clearance for marketing.

The 510(k) pathway is responsible for the majority of device reviews, with the FDA reviewing an average of 31 PMAs and clearing 2,825 devices via the 510(k) pathway per year, with the former focused on revolutionary and the latter focused on incremental innovation.[34] Some public policy advocates note concerns of predicate scope creep,[35] defined as when a 510(k)-cleared devices is substantially different in form or use from its original predicate device which is

[29] Beaver JA, Howie LJ, Pelosof L, et al. A 25-Year Experience of US Food and Drug Administration Accelerated Approval of Malignant Hematology and Oncology Drugs and Biologics: A Review. *JAMA Oncol*. 2018;4(6):849-856. doi:10.1001/jamaoncol.2017.5618

[30] Mehta GU, de Claro RA, Pazdur R. Accelerated Approval Is Not Conditional Approval: Insights From International Expedited Approval Programs. *JAMA Oncol*. 2022;8(3):335–336. doi:10.1001/jamaoncol.2021.6854

[31] Chambers JD, Thorat T, Wilkinson CL, Neumann PJ. Drugs Cleared Through The FDA's Expedited Review Offer Greater Gains Than Drugs Approved By Conventional Process. *Health Aff (Millwood)*. 2017;36(8):1408-1415. doi:10.1377/hlthaff.2016.1541

[32] Beakes-Read G, Neisser M, Frey P, Guarducci M. Analysis of FDA's Accelerated Approval Program Performance December 1992-December 2021. *Ther Innov Regul Sci*. 2022;56(5):698-703. doi:10.1007/s43441-022-00430-z

[33] Moscicki RA, Tandon PK. Drug-Development Challenges for Small Biopharmaceutical Companies. *N Engl J Med*. 2017;376(5):469-474. doi:10.1056/NEJMra1510070

[34] Dubin JR, Simon SD, Norrell K, Perera J, Gowen J, Cil A. Risk of Recall Among Medical Devices Undergoing US Food and Drug Administration 510(k) Clearance and Premarket Approval, 2008-2017. *JAMA Netw Open*. 2021;4(5):e217274. doi:10.1001/jamanetworkopen.2021.7274

[35] Hines JZ, Lurie P, Yu E, Wolfe S. Left to their own devices: breakdowns in United States medical device premarket review. *PLoS Med*. 2010;7(7):e1000280. Published 2010 Jul 13. doi:10.1371/journal.pmed.1000280

often a product years or decades old. Others note safety concerns associated with the incremental regulatory and evidentiary approach of the 510(k) pathway,[36] especially in the setting of recalls of predicate devices.[37,38]

Despite these critiques, a diverse and wide-ranging group of stakeholders[39,40,41] including the FDA itself have noted the need to spend more time, energy, and human capital on "around the corner" regulatory issues such as the regulation of AI/ML, software as a medical device (SaMD), and the blending of software and traditional medical devices. Improving FDA medical device regulation could serve to further promote thoughtful technology assessment and coverage decisions, with historical work noting that Medicare covers devices 80% of the time.[42]

In order to promote evidence generation without creating duplicative work for entrepreneurs and innovators, the FDA needs to improve its 510(k) review program. A key lever is the 510(k) Third Party Review, an agency program dating back to the 1997 FDA Modernization Act. The agency and entities can offload the review of lower complexity devices with low- or moderate-risk to recognized third party review organizations in order to free up agency staff time. Due to a variety of factors, utilization has declined to 2.4% of 510(k) applications in 2020.

The program would benefit from an operational tune-up[43] in order to better focus staff time on more complex applications and the forthcoming wave of digital health and AI/ML-enabled technologies.

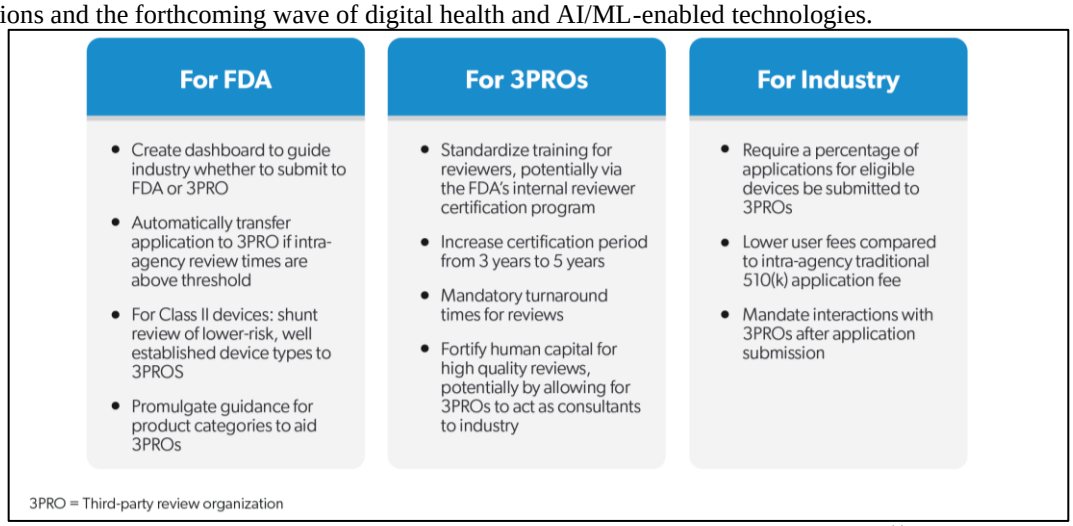

Figure 2: Policy Proposals for the Third Party 510(k) Program[44]

Specifically, the agency could consider a variety of policy options to improve the program, such as improving third party reviewer training by providing access to the agency's internal reviewer training program, creating an interactive dashboard on both third party and FDA review performance, directing a share of specific device categories to review organizations in order to drive volume and quality, creating escape volume and workload-driven escape valves to

[36] Kadakia KT, Beckman AL, Ross JS, Krumholz HM. Renewing the Call for Reforms to Medical Device Safety-The Case of Penumbra. *JAMA Intern Med*. 2022;182(1):59-65. doi:10.1001/jamainternmed.2021.6626
[37] Everhart AO, Sen S, Stern AD, Zhu Y, Karaca-Mandic P. Association Between Regulatory Submission Characteristics and Recalls of Medical Devices Receiving 510(k) Clearance. *JAMA*. 2023;329(2):144–156. doi:10.1001/jama.2022.22974
[38] Kadakia KT, Dhruva SS, Caraballo C, Ross JS, Krumholz HM. Use of Recalled Devices in New Device Authorizations Under the US Food and Drug Administration's 510(k) Pathway and Risk of Subsequent Recalls. *JAMA*. 2023;329(2):136–143. doi:10.1001/jama.2022.23279
[39] Torous J, Stern AD, Bourgeois FT. Regulatory considerations to keep pace with innovation in digital health products. *NPJ Digit Med*. 2022;5(1):121. Published 2022 Aug 19. doi:10.1038/s41746-022-00668-9
[40] Cortez N. Digital Health and Regulatory Experimentations at the FDA. *Yale Journal of Law and Technology*. 2019;21(4):4-26.
[41] Guo C, Ashrafian H, Ghafur S, Fontana G, Gardner C, Prime M. Challenges for the evaluation of digital health solutions-A call for innovative evidence generation approaches. *NPJ Digit Med*. 2020 Aug 27;3:110. doi: 10.1038/s41746-020-00314-2.
[42] Chambers JD, May KE, Neumann PJ. Medicare covers the majority of FDA-approved devices and Part B drugs, but restrictions and discrepancies remain. *Health Aff (Millwood)*. 2013;32(6):1109-1115. doi:10.1377/hlthaff.2012.1073
[43] Miller BJ, Blanks W, & Yagi, B. The 510(K) Third Party Review Program: Promise and Potential. (February 27, 2023). https://ssrn.com/abstract=4383281
[44] See Figure 3 reproduced here from Miller BJ, Blanks W, & Yagi, B, The 510(K) Third Party Review Program: Promise and Potential (February 27, 2023). Available at SSRN: https://ssrn.com/abstract=4383281 or http://dx.doi.org/10.2139/ssrn.43832813

automatically offload applications when FDA is overloaded,[45] and/or permitting organizations to also consult and assist with application compilation. Overall, a more robust third party review program would permit the FDA to reallocate human capital in order to best address a changing device world that will be built around software as a medical device, a policy question that requires thoughtful consideration as to how to best generate evidence to support payer coverage while simultaneously meeting the FDA standard for market entry.

While supporting improvements to the 510(k) pathway are necessary, they are not sufficient. The FDA also needs fit for purpose review pathways for the 21st century world of medical devices in order to better support regulatory efficiency and evidence generation. Current FDA medical device regulatory frameworks date were built in an analog hardware-driven era and are insufficient for a digital world. Just as prescription drugs and biologics have a variety of pathways for product evaluation, medical devices need a similar set of voluntary, alternative pathways.

Specifically, so-called software-driven devices or "integrated devices" (where software serves as a primary driver) could be evaluated through a new voluntary, alternative pathway built around a two-stage review process.[46] In the first stage, independent component review would occur with input, software, and device output components identified and tested independently from each other to see if they meet consensus standards, pass automated testing in a certified lab, pass third party review, or another process. The sum of these "building blocks" would then undergo the second stage of review, or holistic review by the FDA reviewer to ensure that the integrated device functions as intended within its pre-specified performance parameters. For future reviews, previously reviewed component "building blocks" would decrease review time and burden, allowing agency staff to focus on how integrated devices perform in a clinical setting. Similar principles of two stage review (with component review first) coupled with a total product lifecycle approach (TPLC) approach could serve as a basis for a similar voluntary, alternative pathway for pure SaMD/AI.

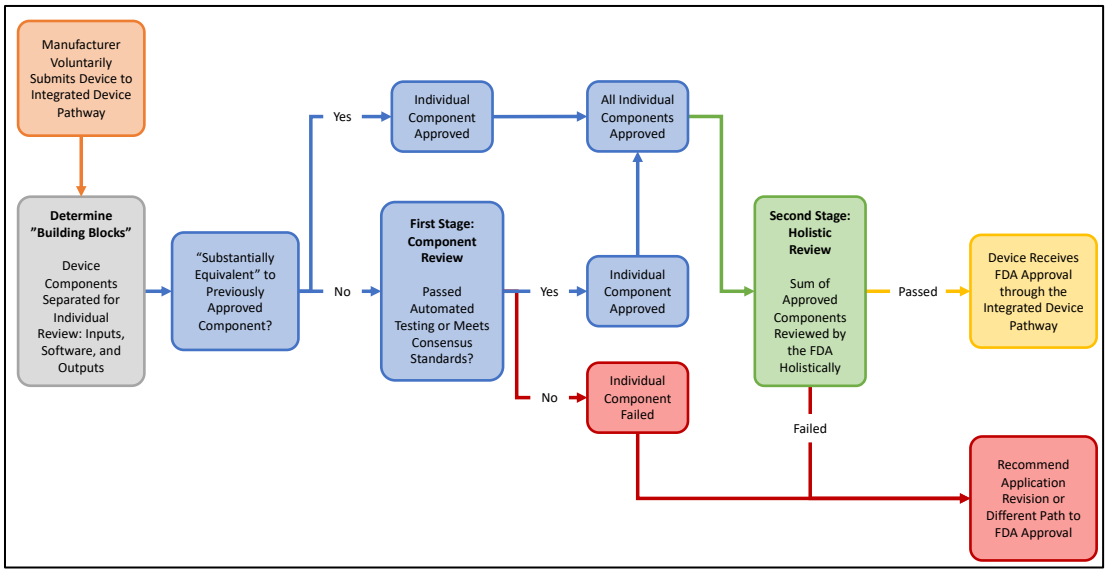

Figure 3: Integrated Device Pathway: A Voluntary, Alternative Pathway[47]

Fit for purpose review pathways offer the potential to both customize the FDA review process and simultaneously permit companies to better tailor evidence to support both FDA approval and Medicare coverage.

[45] Two COVID-19 reviewers committed suicide during the pandemic due to a combination of workload and social isolation. See Eban K. "A Tsunami of Randoms": How Trump's COVID Chaos Drowned the FDA in Junk Science. *Vanity Fair*. (2021). https://www.vanityfair.com/news/2021/01/how-trumps-covid-chaos-drowned-the-fda-in-junk-science

[46] Cho T, Gowda V, Schulzrinne H, & Miller BJ. Integrated Devices: A New Regulatory Pathway to Promote Revolutionary Innovation. (June 21, 2023). https://ssrn.com/abstract=4486757

[47] See Figure 3, Cho T, Gowda V, Schulzrinne H, & Miller BJ. Integrated Devices: A New Regulatory Pathway to Promote Revolutionary Innovation. (June 21, 2023). https://ssrn.com/abstract=4486757

4. The need to think differently about paying for health technology and AI

Telehealth has served as a cautionary tale for our country in how fear and the precautionary principle can crush innovation and destroy access. Historically many reservation about telehealth[48,49] were voiced, including concerns around induced demand, unmet demand, and other features that would drive excessive utilization in a fee for service setting. Prior to the COVID-19 pandemic, Medicare was permitted only to pay for telehealth when the person receiving the service was located in a designated rural area, the beneficiary left their home to go to a medical facility in order to receive care, and the service involved both audio and video communication.[50,51] Early in the pandemic, the Trump Administration waived these restrictions as part of the public health emergency, adding 135 allowable services that beneficiaries could receive via telehealth, removed the originating site restriction, and provided payment at the same rate as in-person visits.[52] The Biden Administration has worked to sustain this broadened scope of telehealth services, and has noted the importance of telehealth in expanding access and combatting health disparities,[53] a pragmatic policy perspective well-supported by emerging health services research.[54] Still others including the American Hospital Association have correctly noted the importance of preserving audio-only telehealth services,[55] correctly pointing out that for many vulnerable Medicare beneficiaries that this serves as a modality complementary to in-person services.

Luckily, as part of the Consolidated Appropriations Act of 2023, the expansion of telehealth services in Medicare was extended through December 31, 2024.[56] Even now, telehealth is an area of rapid innovation and growth, as clinicians and health systems determine how to most efficiently and effectively provide care to patients, a process occurring after decades of delay.

In order to avoid repeating history, policymakers must be proactive in determining how the Medicare programs pays for new technology. Recognizing the need for choice, convenience and clinical appropriateness, ideally beneficiaries will eventually be able to receive care in a variety of modalities:

1. Audio only
2. Audio/video
3. Audio/video with a remote, technology-assisted exam[57]
4. Automated/AI-driven service either remote or in-person
5. Technology-augmented in-person, human capital-driven medical service
6. Human-driven, in-person service

While risk-adjusted capitated programs based upon population-level payments such as Medicare Advantage represent an increasing share of the Medicare marketplace and the future of the program,[58] policymakers must work to ensure that fee for service (FFS) Medicare beneficiaries have equal access to medical technology. Critically, ensuring competition amongst the service provider and modality of care delivery is key to ensuring that beneficiaries have access to the type of care that is best suited to them.

Rather than avoiding paying for technology, policymakers should consider modifications to the FFS Medicare chassis to promote technology competition and augmentation in traditional service delivery modalities in order to expand access and lower cost. For example, a modifier could be added to the physician fee schedule, with an associated

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payment multiplier value set to the type of service provided in order to reflect the differential resources–e.g. 1.0 for in-person, human capital-driven service, 0.80 for a remote A/V visit with a remote exam, 0.60 for automated/autonomous service, and 0.20 for audio-only service. In this way, technology companies, physicians, and health systems would compete in order to offer the most efficient and effective service to Medicare beneficiaries. In other areas such as hospitalizations and similar episodic bundles, technology may be expected to decrease the cost of services, avoiding the need for add-on payments and promoting competition in a mix of human-capital and technology-driven services to promote more efficient care delivery.

While ensuring access to different choices in FFS Medicare is critical, Medicare Advantage plans would likely respond by offering additional flexibility in the modality of care delivery, as evidenced by the marketplace's current focus on offering enhanced financial protections and supplemental benefits. Finally, program integrity is a key component to any expanded set of services, with additional programmatic reforms needed in pre-payment claims editing, improved payment processing infrastructure, and other changes to combat improper payments in the continual, longstanding battle against fraud, waste, and abuse in the Medicare program.

5. Conclusions: A Pragmatic Optimist at Heart

Overall, I am optimistic about life sciences and medical technology innovation improving the lives of Americans enrolled in the Medicare program. Innovation has supported the transition of diseases that are virtual death sentences into chronic conditions, with medical technology and device innovation serving as the next frontier of innovation in making care delivery more customized and convenient. Policymakers should support CMS in making efficient and effective coverage decisions by providing additional guidance, redirecting resources, and by expanding the garden of FDA device review pathways to support earlier evidence generation. Finally, policymakers should support the nascent health technology industries and support competition in care delivery by learning from our country's mistakes in telehealth policy and instead pave a path forward for technology and human capital to work together to make care delivery more customized and convenient for Medicare beneficiaries.