GARDNER
AN FDA LAW FIRM

June 9, 2026

BY ELECTRONIC DELIVERY

The Honorable Dr. Mehmet Oz, MD, MBA
Administrator, Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1849-P
P.O. Box 8013
Baltimore, MD 21244-8013

Re: Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals ("IPPS") and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year ("FY") 2027 Rates; Requirements for Quality Programs; and Other Policy Changes [CMS-1849-P]

Dear Dr. Oz,

We write on behalf of Gardner Law, an FDA law firm that specializes in regulatory, compliance, privacy, commercial, and litigation matters. We counsel medical device and diagnostic companies across all stages of product development, FDA regulatory submission, and commercialization. Our practice spans a broad range of technologies, including implantable devices, diagnostics, capital equipment, AI-enabled medical software, and more. Many of these technologies have pursued, or are actively considering, Breakthrough Device Designation ("BDD") from FDA and New Technology Add-On Payment ("NTAP") eligibility from CMS. We submit these comments in our individual capacity as counsel with direct, firsthand knowledge of how the BDD Alternative Pathway for NTAP has functioned in practice, and how the proposed repeal would affect the companies and patients it currently serves[1].

I. Gardner Law's Perspective and Standing to Comment

Gardner Law represents companies at the intersection of FDA regulatory strategy and Medicare reimbursement planning. Advising clients on NTAP eligibility, including the BDD alternative pathway, is a core component of our practice. We have counseled companies on BDD applications, MEARIS submissions, and commercialization planning relying on the availability of the alternative pathway. We have also advised companies at earlier stages of product development who are making long-term investment and market entry decisions based on the regulatory and reimbursement

[1] 91 Fed. Reg. 19,312 (April 14, 2026); correction at 91 Fed. Reg. 20,397 (Apr. 16, 2026) (extending comment deadline to June 9, 2026).

infrastructure that the BDD alternative pathway offers. This gives our firm a vantage point that is different from, and complementary to, those of device manufacturers filing their own comments.

II. The Proposed Repeal Would Disrupt Settled Reliance at Every Stage of the Product Lifecycle

A critical consequence of the proposed repeal is the damage it will cause to active and prospective applicants currently relying on this pathway, and the chilling effect such a "rug pull" will have on future innovation and investment. Companies do not make FDA regulatory, clinical development, and commercialization decisions in a vacuum. They make them against an established framework of rules that govern how Medicare pays for the technologies they are developing. The BDD alternative pathway is a crucial part of that framework. Since its establishment in the FY 2020 IPPS final rule and its expansion in FY 2021[2], it has become a structural feature of the innovation landscape that companies reasonably and foreseeably rely upon when deciding whether, when, and how to bring a technology to market.[3]

That reliance takes at least three distinct forms, each of which is disrupted by the proposed repeal:

Development-Stage Reliance.

Companies deciding whether to invest in early-stage clinical development weigh expected regulatory pathways against expected reimbursement pathways. A company developing a 510(k)-eligible Breakthrough Device does so knowing that FDA's design for 510(k) clearance does not typically require pre-market clinical trial data, and that the BDD alternative pathway accommodates that framework by not requiring an independent showing of Substantial Clinical Improvement ("SCI") evidence at the time of NTAP application.[4] That knowledge shapes clinical development strategy. A company that might otherwise invest in a modest post-market evidence program, consistent with FDA's framework and the BDD alternative pathway's design, may instead be forced to undertake a substantially more expensive and time-consuming pre-market clinical study if it must satisfy the traditional SCI standard for NTAP. Some companies will conclude that the economics are no longer viable and will choose not to develop the technology at all.

Pipeline Reliance.

The Centers for Medicare and Medicaid Services ("CMS") itself notes in the proposed rule that it received 47 NTAP applications for FY 2027, of which 32 were submitted under the alternative pathway.[5] Those 32 applications represent companies that have already made substantial investments in product development, clinical activities, regulatory submissions, and

[2] *See* 84 Fed. Reg. 42,044, 42,289–92 (Aug. 16, 2019) (establishing the alternative NTAP pathway for qualifying Breakthrough Devices); 85 Fed. Reg. 58,432, 58,602 (Sept. 18, 2020) (expanding the alternative pathway to qualifying antimicrobial products).
[3] CMS reaffirmed the validity of the alternative pathway as recently as November 2025. *See* 90 Fed. Reg. 53,448, 54,013, 54,024 (Nov. 25, 2025) (CY 2026 OPPS/ASC Final Rule).
[4] 84 Fed. Reg. at 42,289–92 (determining that FDA Breakthrough Device Designation is a meaningful and appropriate proxy for the SCI inquiry).
[5] 91 Fed. Reg. at 19,457–59.

commercialization infrastructure. They did so in reliance on the pathway's availability for FY 2028 and beyond. The prospective repeal proposed for FY 2028 applications means these companies may have only one or two NTAP cycles under the pathway before it is eliminated, compressing their timeframe for evidence development and disrupting multi-year planning cycles, which cannot be reversed. The investment already made is not recoverable by the time CMS's proposed effective date arrives.

Post-Market Evidence Reliance.

Perhaps the most important form of reliance is temporal: companies in the BDD alternative pathway cohort are actively building the post-market evidence base that the pathway was designed to enable. As documented in public post-market literature across multiple FY 2022–2025 BDD awardees, this evidence is being generated during and after the NTAP period, exactly as the pathway's design intends. This includes multicenter randomized controlled trials, prospective registries, and large retrospective claims analyses. Repealing the pathway would not undo the evidence commitments these companies have already made, but it would eliminate the reimbursement mechanism that made that evidence generation feasible for the next generation of technologies.

The following table summarizes published clinical evidence for four example Breakthrough Device technologies that received FDA authorization through non-PMA pathways (510(k) clearance or De Novo classification) and NTAP under the alternative pathway. Each technology has produced substantial clinical evidence following authorization and during early commercialization, evidence that extends beyond what was required at the time of initial NTAP approval:

Technology	Manufacturer	NTAP Period	Post-Market Evidence
aprevo Personalized Spine System	Carlsmed	FY 2022–24	• Mullin et al. (n=115, retrospective multicenter cohort) • Sadrameli et al. (n=217, multicenter cohort)
aScope Duodeno	Ambu	FY 2022–24	• Forbes et al., (n=518, ICECAP randomized controlled trial () • Hutfless et al. (n>823,000, Medicare claims analysis)
iFuse Bedrock Granite Implant System	SI-BONE	FY 2023–25	• Eastlack et al. (n=6,907,post-market surveillance study) • Caridi et al., (n=122, prospective registry study [PAULA])
Phagenyx Neurostimulation System	Phagenesis	FY 2024–26	• Harvey et al., (PHEED randomized controlled trial)

These are not modest evidentiary commitments, but include multicenter randomized controlled trials, large-scale claims analyses, and prospective registries. Critically, this evidence was generated *because* the BDD alternative pathway enabled hospital adoption during the NTAP period, which created the patient volume necessary to drive these studies. The causal relationship runs from reimbursement access to evidence generation, not the other way around.

Gardner Law's experience advising companies across this landscape confirms this mechanism at work. NTAP payment support reduces the financial friction that otherwise discourages hospitals from adopting new technologies during the early launch window when Medicare Severity Diagnosis Related Group ("MS-DRG") payment may not yet reflect the added cost of the technology. That early adoption generates the case volume, surgeon familiarity, and institutional infrastructure necessary to conduct meaningful post-market clinical studies. Without the initial NTAP-supported adoption, the patient populations needed to fill multicenter trials and registries simply do not materialize quickly enough to produce the evidence CMS now points to as lacking. The pathway was designed to enable this sequence, and the evidence in the table above demonstrates that it is working as intended.

III. The Proposed Repeal Would Harm Medicare Beneficiaries, and No Existing or Announced Program Fills the Gap

The Medicare program exists to ensure that its beneficiaries have access to medically necessary treatments, including those at the frontier of clinical innovation. The BDD alternative pathway for NTAP serves that mission directly. By enabling hospitals to adopt breakthrough technologies during the early commercialization window when MS-DRG payment does not yet reflect the cost of the device, the pathway ensures that Medicare beneficiaries can access technologies that FDA has determined address life-threatening or irreversibly debilitating conditions with unmet clinical need. Repealing the pathway narrows that access, and every downstream consequence of the proposed repeal ultimately resolves to the same harm: Medicare beneficiaries will wait longer, and in some cases indefinitely, for breakthrough technologies that the federal government's own expert scientific agency has already determined they need.

Moreover, the technologies at issue are not marginal. The devices identified in the evidence table in Section II address conditions affecting some of Medicare's most vulnerable beneficiaries: spinal deformity requiring complex surgical intervention, hospital-acquired infection from contaminated duodenoscopes, sacroiliac joint dysfunction in the setting of degenerative spinal disease, and post-stroke dysphagia. These are not elective or lifestyle technologies; they are clinically serious interventions for which FDA granted Breakthrough Device Designation precisely because existing treatments are inadequate. When hospitals decline to adopt these technologies because the economics of early-stage reimbursement do not support it, Medicare beneficiaries bear the

consequence.

Such consequence is the predictable and well-documented result of the financial dynamics that NTAP was designed to address. When the cost of a new device exceeds the MS-DRG payment rate, hospitals face a per-case financial loss for every beneficiary who receives it.[6] That loss creates a rational institutional disincentive to adopt the technology. The practical effect is a narrowing of access that falls disproportionately on beneficiaries treated at community hospitals and in underserved settings where cost sensitivity is highest. The BDD alternative pathway mitigates that dynamic by providing supplemental payment during the critical early adoption window. Removing it restores the financial barrier and, with it, the access disparity.

The recently announced Regulatory Alignment for Predictable and Immediate Device ("RAPID") pathway does not change this calculus. RAPID addresses whether Medicare will cover a technology through a national coverage determination; it does not address how much Medicare pays hospitals to use it. These are different problems, and solving one does not solve the other. A favorable coverage determination means little to the beneficiary whose hospital cannot afford to offer the device because the MS-DRG rate does not cover its cost. Moreover, RAPID's eligibility requirements — including an Investigational Device Exemption ("IDE") study enrolling Medicare beneficiaries and, for Class II devices, enrollment in FDA's Total Product Lifecycle Advisory Program ("TAP") pilot — may render the program structurally unavailable to many 510(k)-cleared Breakthrough Devices, which by regulatory design do not have IDE studies. The program has also not yet been formally proposed through the Federal Register[7], its operational details remain undefined, and its implementation depends on an FDA that has experienced significant leadership transition since the program's announcement, including the departure of the Commissioner under whose leadership it was designed. None of this reflects on RAPID's merits as a concept, but it does mean the program cannot, at this time, be credited as a substitute for the pathway CMS proposes to repeal.

The net result is a gap during which Medicare beneficiaries lose access to the reimbursement mechanism that enables hospitals to offer breakthrough technologies during the early adoption window. Some beneficiaries will experience delayed access. Others, particularly those treated at cost-sensitive community hospitals, may never receive the technology at all. In the most consequential cases, manufacturers will conclude that the economics no longer support commercialization without adequate early-stage reimbursement, and the technology will not reach the market. In each scenario, the person who bears the cost is the Medicare beneficiary — the person the entire system exists to serve. That outcome is inconsistent with the Medicare program's

[6] By statute and regulation, NTAP is capped at the lesser of (i) 65% of the cost of the new technology, or (ii) 65% of the amount by which the cost of the case exceeds the standard DRG payment, for no more than three years. *See* 42 U.S.C. § 1395ww(d)(5)(K); 42 CFR § 412.88.

[7] As of the date of this letter, RAPID has been announced via joint CMS-FDA press release (Apr. 23, 2026) but has not been published in the Federal Register as a proposed rule or guidance document, and its operational details — including application procedures, evidentiary requirements, and timelines — remain undefined.

foundational purpose.

The proposed repeal would also undermine America's global competitiveness in medical technology innovation. Other countries, including China, have made the development of globally competitive medical technologies a strategic priority. Eliminating a reimbursement pathway that supports early adoption of FDA-designated breakthrough technologies would weaken the U.S. innovation ecosystem, harm the American economy, and threaten the United States' position as the world leader in developing, commercializing, and deploying advanced medical technologies.

IV. The Proposed Repeal Would Penalize Compliance with FDA's Regulatory Framework

From an FDA regulatory perspective, the most troubling aspect of the proposed repeal is what it implies about 510(k) clearance itself. The 510(k) pathway is not a lesser form of FDA authorization; it is the appropriate pathway for devices that are not Class III and do not require premarket approval. For technologies that receive both Breakthrough Device Designation and 510(k) clearance, FDA has made two pertinent determinations[8]: first, that the device provides for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or condition; and second, that the device is substantially equivalent to a legally marketed predicate device (i.e., the device has the same intended use and does not raise different questions of safety and effectiveness compared to the predicate). Both determinations are the outputs of a rigorous federal process conducted by the agency Congress designated to make exactly these judgments.

Requiring that a 510(k)-cleared Breakthrough Device also satisfy the CMS SCI standard at the time of NTAP application imposes a third evidentiary requirement that neither FDA nor Congress designed for 510(k) devices. It conditions Medicare reimbursement support on the availability of clinical trial evidence that, by the structure of the 510(k) pathway, has not yet been generated. In the proposed repeal, CMS is creating an inconsistency between the regulatory framework FDA administers under the Federal Food, Drug, and Cosmetic Act, and the payment framework CMS administers under the Social Security Act. Both agencies serve Medicare beneficiaries, yet the framework they administer under this repeal would be internally inconsistent, if not expressly contradictory.

Moreover, through its IPPS rulemaking, CMS has developed a 'newness' criterion under which a technology must not be 'substantially similar' to an existing technology based on factors including mechanism of action, MS-DRG assignment, and the disease or patient population treated.[9]

That inquiry is analytically distinct from FDA's determination of "substantial equivalence" under the 510(k) pathway, which addresses whether a device has the same intended use and similar technological characteristics as a legally marketed predicate. A technology can be substantially

[8] *See* Federal Food, Drug, and Cosmetic Act § 515B(b), 21 U.S.C. § 360e-3(b) (Breakthrough Device Designation criteria); *id.* § 510(k), 21 U.S.C. § 360(k) (substantial equivalence standard for 510(k) clearance).
[9] *See, e.g.*, 42 CFR § 412.87(b)(2) (newness criterion); 85 Fed. Reg. 58432, 58602 (Sept. 18, 2020) (substantially similar analysis).

equivalent to a predicate for FDA clearance purposes and still be "new" for NTAP purposes. These are different tests, administered by different agencies, under different statutory authorities, for different purposes. Any suggestion that 510(k) clearance, by virtue of its predicate-comparison framework, is inherently inconsistent with NTAP eligibility conflates two standards that Congress and the agencies themselves have kept separate.

Furthermore, the 21st Century Cures Act[10], reflects Congressional judgment that the federal regulatory framework for innovative medical technologies should promote access and accommodate the reality that clinical evidence develops over the lifecycle of a device. The BDD alternative pathway for NTAP is the CMS implementation of that congressional judgment. Its repeal would reverse that implementation.

V. The Administrative Record Does Not Support Repeal

Gardner Law agrees with the comments submitted by the Medical Device Manufacturers Association[11] and individual manufacturers that the proposed repeal lacks a sufficient evidentiary basis. CMS has not identified programmatic failures, adverse outcomes, program integrity concerns, or cost overruns associated with technologies approved under the alternative pathway. It has not presented comparative data showing that alternative pathway technologies underperform relative to traditionally approved technologies on clinical or economic metrics. It has neither quantified the benefit it expects to achieve from repeal nor weighed that benefit against the costs in disrupted innovation, reduced hospital access, and foregone evidence generation.

From a legal standpoint, this absence is significant. Under *Motor Vehicle Manufacturers Ass'n v. State Farm Mutual Automobile Insurance Co.,* 463 U.S. 29 (1983)[12], an agency acts arbitrarily and capriciously when it fails to consider an important aspect of the problem. The reliance interests of companies that have made investments and pipeline decisions based on the availability of the BDD alternative pathway are an important aspect of this problem. The structural function the pathway serves in enabling post-market evidence generation is an important aspect of this problem. Neither is addressed in the proposed rule. That is a vulnerability in the administrative record that CMS should resolve before finalizing any repeal.[13]

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[10] Pub. L. No. 114-255, § 3051, 130 Stat. 1033, 1121–24 (2016) (codified at 21 U.S.C. § 360e-3)
[11] *See* Letter from Mark Leahey, President & CEO, Medical Device Manufacturers Association, to Administrator Oz, Re: CMS-1849-P (June 9, 2026).
[12] 463 U.S. 29, 43 (1983) ("Normally, an agency rule would be arbitrary and capricious if the agency has…entirely failed to consider an important aspect of the problem.")
[13] *See also Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221 (2016) (holding that an agency must provide a reasoned explanation for "disregarding facts and circumstances that underlay or were engendered by the prior policy"); *DHS v. Regents of the Univ. of Cal.*, 591 U.S. 1, 30 (2020) (holding that when reversing a prior policy, an agency must assess whether reliance interests exist, determine their significance, and weigh them against competing policy concerns). The proposed rule contains no such analysis. *See* 91 Fed. Reg. at 19,457 (stating only that CMS has developed "concerns with the limited evaluation process for alternative pathway applications" based on unspecified "experience gained")

VI. Conclusion

Gardner Law respectfully urges CMS to withdraw its proposal to repeal the BDD alternative pathway for NTAP. The pathway has functioned as designed, has not been shown to have failed, and its repeal would impose substantial and unjustified costs measured in disrupted innovation, frustrated reliance, inconsistency with FDA's regulatory framework, and Medicare beneficiary harm.

Should CMS determine that modifications are warranted, we strongly encourage a reconsideration of this proposed repeal, or at least support a delay to derive a more measured, defensible, and substantively improved alternative to full repeal. This approach would preserve the pathway's intended function while providing CMS the evidentiary accountability mechanism it seeks, without the collateral consequences of repeal.

Gardner Law welcomes the opportunity to discuss these comments with CMS staff and to provide additional information based on our firm's experience advising companies across the BDD and NTAP landscape.

Respectfully submitted,

/s/

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