CAPITOL STREET

April 12, 2026

2027 MedTech & Biopharma Policy In Proposed Hospital Inpatient Rule

Negative New Tech (NTAP) and Pass-Through Proposal: Breakthroughs No Longer Automatically Considered Significant Improvement

Relevant Companies: MEDTECH AND BIOPHARMA

Our Take & Next Up

One anti-innovation surprise negatively affects some medical device manufacturers: CMS is proposing to eliminate the flexibilities allowed under the "alternative pathway" for new tech add-on payments (NTAP), starting with FY 2028 applications. If finalized, all applicants for NTAPs would have to meet all criteria requirements to receive add-on payments (newness, substantial clinical improvement, costs). This is likely to significantly shrink the number of NTAP eligible products and future designations will be harder to achieve even for breakthrough products.

For FY 2027, eight (8) new + twenty-two (22) alternative pathway new technology add-on payment (NTAP) determinations are proposed. CMS estimates that additional payments for inpatient cases involving new technologies will increase by about $464 M in 2027, driven primarily by the continuation of new technology add-on payments.

CMS's proposed nationwide expansion of its mandatory joint replacement model, CJR-X, would require most hospitals to assume financial responsibility for hip, knee, and ankle procedures, including 90 days of post-operative care. CJR-X is expected to create near-term financial pressure for providers, with likely net losses in the first year due to penalties and rising costs. Post-acute providers face significant risk, as hospitals may achieve savings by reducing follow-up care and shifting to lower-cost sites of service (e.g., home health). CMS projects the model will generate $725 M in savings over five years.

Key Points

For FY 2027, CMS is proposing to increase inpatient pay by +1% for for-profit hospitals. CMS issued the proposed IPPS and LTCH payment rules (here) on April 10 after the close. Our inpatient hospital analysis is incoming. Final rates will be released on or around August 1, 2026. Payment rates and policies for FY 2027 starts Oct 1, 2026.

CMS proposes repealing the Alternative NTAP Pathway (New Technology Add-On Payments), requiring all applicants to meet eligibility criteria (newness, cost, substantial clinical improvement). The "alternative pathway" allows certain devices and antimicrobials to qualify for new technology add-on payments without having to demonstrate substantial clinical improvement. Starting FY 2028, all technologies would need to meet the full eligibility criteria — including FDA marketing authorization by May 1 of the prior year. We note that a majority of NTAP applications come from the alternative pathway. If finalized, this further limits eligibility for the additional payment and closes a lane that was available to breakthrough-designated devices and certain antimicrobials.

CJR EXPANSION

CMS is proposing the first mandatory, nationwide test of an episode-based payment model via Comprehensive Care for Joint Replacement model, called CJR-X. This would be a national expansion of the already mandatory Comprehensive Care for Joint Replacement model. The initial CJR model ran from April 2016 through December 2024 and was estimated to have generated about $112.7 M in net Medicare savings.

The CJR-X bundled payment would cover hospitalization, the procedure, and most post-acute services (starting October 2027). The model sets payments for hip, knee and ankle replacements via a 90-day episode-based payment structure. If finalized, the model would begin in October 2027 and is expected to include most hospitals. Participating hospitals would be held accountable for total costs and outcomes, incentivizing better care coordination, transitions between care settings, and reducing avoidable readmissions.

Providers (particularly in post acute) are likely to see further margin compression from bundled payments on joint procedures. As in CJR and the Bundled Payments for Care Improvement Advanced models, episode spending would be compared to a target price to determine whether the hospital receives a reconciliation payment or owes a penalty back to CMS. This penalty will likely impact hospitals particularly in the first few transitional years when they may lack the structure or model experience to change their delivery of joint replacement care. As the bundled payments cover most post-acute services, post acute care providers are also likely to see pressure on their reimbursement for common joint procedures.

Hospitals participating in the mandatory Transforming Episode Accountability Model (TEAM) will be exempt (until 2031). Under TEAM, selected acute care hospitals will receive episode based payment from surgery through 30 days post-hospitalization for five surgical procedures: lower extremity joint replacement, surgical hip femur fracture treatment, spinal fusion, coronary artery bypass graft, and major bowel procedures. CMS will exclude hospitals that receive bundled TEAM payments and participants would shift to CJR-X after the TEAM model ends in 2030.

PROPOSED NTAPS

22 new alternative pathway products are being considered for NTAP approval (e.g., Breakthrough, QIDP, or LPAD approval). All of the applications received Breakthrough Device designation.

- **CMS is proposing coverage for 22 products.** Bayesian Health Sepsis Flagging Device (Bayesian Health), BriefCase-Triage: CARE Multi-Triage CT Body (Aidoc Medical), CARA System (Cara Medical), CERAMENT V (BoneSupport), Delirium Monitor System (CBLL), CMORE CT System (Icotec), GORE VIABAHN FORTEGRA Venous Stent (Gore Medical), Infuse Bone Graft (MDT), InVision Precision Cardiac Amyloid (Invision Medical Technology), MediBeacon Transdermal GFR Measurement System

(VATE), MicroStent and the MicroStent XL Peripheral Vascular Stent System (Micro Medical Solutions), Nelli Seizure Monitoring System (Neuro Event Labs), NEXUS Aortic Arch Stent Graft System (EndoSpan), OmniaSecure MRI SureScan Lead Model 3930M (MDT), PearlMatrix P-15 Peptide Enhanced Bone Graft (Cerapedics), PMcardio STEMI AI ECG Model (Powerful Medical), SAPIEN M3 TMVR System (EW), SetPoint System (SetPoint Medical), Spur Peripheral Retrievable Stent System (Reflow Medical), Trilogy Transcatheter Aortic Valve Regurgitation System (JenaValve), ViaOne Epicardial Access System (CardioVia), and DeepCARS (VUNO Med).

8 new traditional products are also being reviewed for traditional NTAP approval. Applicants must have received FDA marketing authorization by May 1 of the prior fiscal year.

- These include COBENFY (BMY), Command Center Electronic Glycemic Management System (Glytec), GAMIFANT (SOBI), Orca-T (Orca Bio)**,** RAPIBLYK (AOP Health), WASKYRA (Fondazione Telethon), YARTEMLEA (OMER), and ZEVASKYN (ABEO).

41 products will keep their NTAP designation. A reminder, the add-on payment is lesser of (1) 65% of the costs of the new tech or (2) 65% of the amount by which the costs of the case exceed the standard MS-DRG payment. This percentage is increased to (1) 75% for Qualified Infectious Disease Products (QIDPs) or products approved under the Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD) pathway, or for gene therapies.

- Annalise Enterprise Computed Tomography Brain (CTB) Triage – OH (Harrison.ai Radiology), ASTar System (QLINEA), Edwards EVOQUE Tricuspid Valve Replacement System (EW), GORE EXCLUDER Thoracoabdominal Branch Endoprosthesis (Gore Medical), LimFlow System (SYK), Paradise Ultrasound Renal Denervation System (Otsuka Medical Devices), PulseSelect Pulsed Field Ablation (PFA) Loop Catheter (MDT), Symplicity Spyral Multi-Electrode Renal Denervation Catheter (MDT), TriClip G4 (ABT), VADER Pedicle System (Icotec), ZEVTERA (INVA), Casgevy (VRTX & CRSP), HEPZATO KIT (DCTH), Lyfgenia (BLUE), 4WEB Medical Ankle Truss System (SYK), AeroPace System (Lungpacer Medical), AGENT Paclitaxel-Coated Balloon Catheter (BSX), alfapump system (SEQUA), aprevo-C cervical interbody fusion device (CARL), CERAMENT G (BoneSupport), Emily's Care Nourish Test System (Model 1) (Lactation Lab), Esprit BTK Everolimus Eluting Resorbable Scaffold System (ABT), EUROPA Posterior Cervical Fusion System (MiRus), iFuse TORQ TNT Implant System (SIBN), Merit Wrapsody Cell Impermeable Endoprosthesis (MMSI), Minima Stent System (Renata), MY01 Continuous Compartmental Pressure Monitor (MY01), PBC Separator with Selux AST System (SeLux Diagnostics), restor3d TIDAL Fusion Cage (Restor3d), ShortCut (Pi-Cardia), The WiSE CRT System (EBR), TriVerity Test (Inflammatix), VITEK REVEAL AST System (bioMérieux), EMBLAVEO (ABBV), CONTEPO (meitheal pharmaceuticals), AURLUMYN (SERB Pharmaceuticals), BREYANZI (BMY), GRAFAPEX (MDP), IMDELLTRA (AMGN), TECELRA (US WorldMeds).

12 products will lose their NTAP designation as their 3-year anniversary date will occur before April 1, 2027. NTAP designations set to expire are below.

- CYTALUX (On Target Laboratories), EPKINLY and COLUMVI (ABBV), Aveir AR Leadless Pacemaker (ABT), Aveir Dual-Chamber Leadless Pacemaker (ABT), Ceribell Status Epilepticus Monitor (CBLL), DETOUR System (Endologix), DefenCath (CRMD), Phagenyx System (Phagenesis), REZZAYO (CDTX), SAINT Neuromodulation System (Magus Medical), TOPS System (Premia Spine), XACDURO (INVA).

1 product will lose its NTAP designation as its 3-year anniversary date will occur before October 1, 2026. NTAP designation set to expire is below.

- RECELL Autologous Cell Harvesting Device (RCEL)

Ipsita Smolinski
Managing Director I Capitol Street
ipsita@capitol-street.com

202.250.3741 I www.capitol-street.com

900 19th St NW 6th Fl
Washington, D.C. 20006

CAPITOL STREET

Copyright 2026 Capitol Street.

This communication, including this broadcast and any attachments hereto, is intended solely for the original recipient(s) and may not be redistributed without the written consent of Capitol Street. This communication is for informational purposes only and is not intended as an offer or solicitation for the purchase or sale of any financial instruments, nor is it intended as advice to purchase or sell such instruments