TIBER CREEK GROUP

TCG'S HEALTHCARE OUTLOOK:

What to Watch this Fall

August greetings from Washington, D.C. The policy agenda for the fall is shaping up as Congress prepares for the midterm elections. While little congressional activity on healthcare is expected before the elections, the conditions are ripe for an attempt at a lame duck healthcare package and lawmakers are starting to think about priorities for the 120th Congress. Meanwhile, continued administrative activity is expected on fraud, drug pricing policy, health tech, MAHA, and more. Read on for Tiber Creek's insights on the latest and what's coming up across the health policy sector.

The Legislative Outlook

- **There are few legislative days left before the midterms,** and healthcare is unlikely to be a focus – at least until lame duck. When they return from August recess, lawmakers will prioritize extending government funding beyond the end of the fiscal year on September 30 through a Continuing Resolution. Reconciliation 3.0 remains a possibility, but based on the House-passed budget resolution, healthcare is unlikely to be included in a final bill.

- **One healthcare priority: nominations.** Senate Finance will schedule a hearing on Chris Klomp's nomination to be Deputy Secretary of Health and Human Services (HHS), and the Senate Health, Education, Labor, and Pensions (HELP) Committee will work to line up a hearing on the nomination of Heidi Overton to lead the Food and Drug Administration (FDA). Klomp appears likely to be confirmed, but Overton may face an uphill battle given HELP Chairman Bill Cassidy's (R-LA) "strong concern" about her role in a recent executive order (EO) on vaccines, which he suggests may be disqualifying on its own.

- **Summer saw a flurry of markups and hearings** as healthcare committees processed legislation in anticipation of a year-end legislative package. We expect this activity to continue in September. Healthcare extenders expiring at the end of this calendar year, including the one-year 2.5 percent Medicare physician payment boost, the Advanced Alternative Payment Model bonus, the delay of lab cuts, and funding for Community Health Centers, among others, could form the basis of a larger package. **See our tracker of all the healthcare bills marked up but not yet enacted so far in 2026,** here, for what we're watching as possible inclusions if a package does come together.

- **Congress appears to be inching closer to action on a few topics:**

    - **Medicare physician payment reform** is a perennial issue for Congress. A handful of bipartisan bills, including the Patients First Act, led by co-chairs of the GOP and Democrats' Doctors Caucuses, and the Provider Reimbursement Stability Act indicate Congress' desire to pursue long-term reform on this issue. A significant hurdle for any physician payment reform effort will be paying for it, and there are some rumblings that anti-fraud policies, like a new bill introduced by Sens. Catherine Cortez Masto (D-NV) and Chuck Grassley (R-IA), could be used as a payfor. Congress may be further spurred into action when the final 2027 Physician Fee Schedule (PFS) is released, typically by the end of October, especially if the pay cut matches or exceeds the up to 1.68% cut proposed earlier this year. **See our one-pager on the proposed PFS,** here.

- **The 340B drug discount program** is another area where Congress has long sought to make reforms. Congressional activity on 340B steadily ticked up this summer, as Senate HELP Chairman Cassidy released his 340B for Patients Act discussion draft in June, a House bipartisan working group introduced the SECURE 340B Act in July, and the Senate's "Gang of Six" bipartisan working group reintroduced the SUSTAIN 340B Act in August. **See TCG's comparison chart of four 340B reform bills,** here. None of these proposals are expected to be signed into law by the end of the year, but with champions sitting on key healthcare committees, a hearing on 340B would be unsurprising this fall. Conversations in the next few months will lay the groundwork for continued work on 340B in the 120th Congress.

- **Transparency has emerged** as a bipartisan priority this year. The Senate HELP Committee marked up the Patients Deserve Price Tags Act, to require providers, plans, and pharmacy benefit managers to publicly post prices charged to patients, along with the CLEAR Labels Act, which would add requirements for country-of-origin information on pharmaceutical labeling. **See our summary memo of the HELP markup,** here. In the House, the Energy and Commerce (E&C) Committee advanced the bipartisan Lower Costs, More Transparency Act, which was amended to include bills on price transparency, prior authorization in Medicare Advantage, premium and plan cost transparency, and more. The committee also advanced the Prices on the Walls Act, which would require certain providers to list prices for care on their walls. **See our summary memo of the E&C markup,** here. Lawmakers could include these and other bipartisan priorities in a year-end health package.

*Developments for **Drugs and Devices***

- **Most-Favored-Nation (MFN) policy is poised for a return to the spotlight** after a relatively quiet period following the April announcement of the White House's 17th drug pricing agreement. In June, the Office of Management and Budget received the proposed GLOBE and GUARD Models for final review, which would test MFN-aligned rebates for Medicare Parts B and D, but they have yet to be finalized, and the White House has been pursuing deals with smaller and midsize companies throughout the summer with an announcement expected at the end of August. Additionally, states have until September 10, 2026 to apply to participate in the GENEROUS Model, which tests MFN-aligned rebates in Medicaid. Any further deals will have implications for Section 232 tariffs (more on that below) and for GLOBE and GUARD, and we are watching to see what the Administration does with the models alongside a potential slate of deals.

- **Drug and device makers face looming Section 232 deadlines** later in August and in September. By statute, the Administration has until August 28 to announce actions pursuant to the Section 232 investigation on personal protective equipment, medical consumables, and medical devices launched last September. On the pharma side, the first implementation date for the President's tariffs on branded drugs passed with little fanfare on July 31: until the next phase-in, only the 17 companies with current drug pricing deals are subject to the tariffs, and all 17 companies appear to be exempted, by virtue of their agreements with the White House, drug-specific carveouts, and country-level exemptions. But starting September 29, all other drug companies will face a 100 percent tariff unless they qualify for one or more exemptions like those based on drug indication, a country-level trade deal, an onshoring agreement with the Department of Commerce, or a drug pricing agreement with the Administration.

- **The Administration finalized a proposal to require Breakthrough Devices** demonstrate novelty and substantial improvement over existing alternatives to qualify for supplemental payments under the New Technology Add-on Payment (NTAP) and Transitional Pass-Through Payment (TPTP) starting in 2028 as part of the final fiscal year (FY) 2027 inpatient hospital prospective payment system (IPPS) rule. **See TCG's resource on the rule,** here. The Centers for Medicare and Medicaid Services (CMS) also issued a notice on the new RAPID Pathway, under which certain Breakthrough Devices could receive FDA marketing authorization and a proposed National Coverage Determination from CMS on the same day. Thus far, the RAPID announcement has received generally positive feedback, with some disappointment that in vitro diagnostic (IVD) devices were carved out of the program. The agency will accept comments on the RAPID framework until October 13.

*An Update on **Interoperability and Technology***

- **CMS celebrated one year of the Health Technology Ecosystem (HTE)** earlier this summer. The initiative aims to help industry voluntarily collaborate and innovate to create an interoperable system for health data that leads to consumer empowerment and better coordinated care. The HTE boasts about 800 participant organizations aligned to more than a dozen pledges, covering data networks, electronic health record (EHR) companies, patient facing apps, payers, pharmacies, providers, and patients, and topic-focused pledges on issues like clinical trial matching, scheduling, prior authorization, and diagnostic imaging. CMS indicated at a recent event that the next year of HTE will focus on driving adoption of new tools and interoperable systems.

- **CMS is also promoting interoperability in regulation** alongside the voluntary structure of the HTE. In the final FY27 IPPS rule, CMS and the Office of the National Coordinator for Health Information Technology (ONC) finalized a series of health IT standards that were originally included in the 2026 Interoperability Standards and Prior Authorization for Drugs proposed rule, along with several changes to the Medicare Promoting Interoperability Program. These and other steps reflect CMS' continued focus on health tech and interoperability, and we expect this to remain a priority for the Administration this fall.

- **Wearables, artificial intelligence (AI), and consumer access to data remain key elements of HHS' agenda.** While the HTE forms the backbone of CMS' efforts to empower consumers with data, other agency initiatives like the patient health-tech focused ACCESS Model, the use of AI tools to drive fraud prevention, and the FDA's latest regulatory discussion paper on how to regulate AI medical devices represent HHS' department-wide approach to technology.

*The **MAHA** Agenda*

- **Food and nutrition remain the centerpiece** of HHS Secretary Robert F. Kennedy, Jr.'s Make America Healthy Again (MAHA) Agenda. Recent food and nutrition milestones include changes to the "generally recognized as safe" standard for food ingredients and steps towards defining "ultra-processed food." Sec. Kennedy also launched a cooking show aligned with new dietary guidelines from the Administration and a podcast with celebrity guests.

- **Activity on vaccines and autism** increased after what appeared to be a cooling off period this summer. In early August, President Trump signed an EO directing agencies to implement a childhood vaccine schedule that would reduce the number of vaccines recommended for all children from 18 to 11 and call for single-disease vaccinations against measles, mumps, and rubella instead of the current combined vaccine against all three diseases. At the EO signing, Sec. Kennedy and other officials reiterated suggestions that childhood vaccines could contribute to autism, though the EO itself is absent of any such statements.

- **The EO came days after Dr. Erica Schwartz was sworn in** as the new Director of the Centers for Disease Control and Prevention (CDC), ending a nearly year-long void of permanent leadership at the agency. The CDC's previous head, Dr. Susan Monarez, was fired after less than a month on the job when she objected to approving vaccine policy decisions she held were not backed by science. Vaccines were a central theme at Dr. Schwartz's confirmation hearing where she consistently held she would "follow the science" and act with integrity. **Read our summary memo of her nomination hearing,** here. Dr. Schwartz is now faced with what could be a major test of those statements in how she handles this latest vaccine EO.

*What's Next for **Medicaid***

- **CMS' Medicaid Fraud War Room** (MFWR) had a busy summer: the initiative claimed to have stopped more than $203 million in potentially improper payments since it was launched in April, taking actions against 50 Medicaid providers. CMS also deferred an additional $1 billion in Medicaid funds to Minnesota and California in July – the second such deferral for California, and third for Minnesota – and released a "toolkit" to address fraud related to behavioral services for children with autism. In Congress, Senate Budget Chairman Ron Johnson (R-WI), who took over for the late Sen. Lindsey Graham (R-SC), held his first hearing as chairman on Medicaid fraud (**see TCG's summary memo,** here). Expect a steady drumbeat on fraud throughout the fall, including CMS' forthcoming proposed Comprehensive Regulations to Uncover Suspicious Healthcare (CRUSH) Fraud rule, as Republicans center these efforts in midterm messaging.

- **States are watching for a revised Medicaid Work Requirements final rule** following the end of the comment period on the interim final rule on July 31. CMS may update the rule incorporating stakeholder feedback, but time is growing short for states to implement work requirements by January 1, 2027, especially if CMS changes its guidance once again. **For more on the interim final rule, see TCG's key takeaways,** here. More changes are coming to Medicaid through new or revised rules on provider taxes, state-directed payments, and eligibility required by the One Big Beautiful Bill Act (OBBBA), signed into law last summer. **See our one-year check-in on OBBBA implementation,** here.

The 2026 Midterms: ***Impacts for the 120th Congress & Beyond***

- **Changes are coming to key committee leadership and membership** as congressional turnover hits a high point: at least 83 incumbents will not return to their seats in January. Earlier this summer, Senate HELP Chairman Cassidy lost his primary, and questions remain about who will take over the gavel. At least two other seats on the committee will be vacant. Senate Finance leadership is likely set, but the committee will see at least five vacancies heading into the 120th Congress. **See TCG's Senate Musical Chairs document for** more. On the House side, key health leadership positions will open as the top Democrats on the House E&C and House Ways and Means (W&M) Health Subcommittees will not return, which is especially impactful if Democrats win control of the House. Several vacancies will open on both E&C and W&M, as well, though final numbers will depend on party control. If Democrats take the majority in the House, we could see 12 or more vacancies for Democrats on W&M and nine on E&C.

- **Democrats are looking beyond the midterms to 2028** as they build consensus around healthcare policies in preparation for their next meaningful opportunity to enact their priorities.

    - **House Democrats** organized five affordability working groups this spring, including one on healthcare led by Reps. Terri Sewell (D-AL) and Alexandria Ocasio-Cortez (D-NY). If Democrats control the House starting in 2027, they may prioritize some policies developed by the working groups, but enactment is unlikely without control of the Senate and White House, as well.

    - **On the Senate side**, Senate Finance Committee Ranking Member Ron Wyden (D-OR) is leading three separate workstreams alongside a large swath of the Senate Democratic Caucus, focused on prescription drug prices, commercial insurance, and long-term care. This summer saw the release of two Requests for Information (RFI), the first aligned with the drug pricing workstream and the second with the commercial insurance workstream, as Senate Democrats coalesce around their health policy platform of the future. **See our key takeaways on the drug pricing RFI** here**, and on the commercial insurance RFI** here.

Conclusion

Fall will bring annual Medicare payment updates, congressional activity on priority areas like physician pay reform and 340B, developments for pharmaceutical products, health tech, and medical devices, and more against the backdrop of the midterm elections and an influx of new faces in Congress come January. Your team at Tiber Creek will keep track of developments in healthcare policy on Capitol Hill and in the Trump Administration. We're available to help you navigate the details and activities relevant to your work and your organization.

If you have questions on any of these topics, please don't hesitate to contact any one of us.

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