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2025 The Biggest Year in Healthcare: What to Watch Lame Duck 2024

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We believe that 2025 will be the biggest year in healthcare since the failed Affordable Care Act (ACA) "Repeal and Replace" debate in 2017. Below we list the key reasons why:

- **ACA Enhanced Subsidy Expiration:** We expect the expiration of the ACA enhanced subsidies at the end of 2025 to drive serious conversations around either extending or phasing-out these subsidies; the Congressional Budget Office (CBO) has scored an extension of the subsides as costing the government $335 billion over ten years. We believe that a Republican-led Congress may look to authorize a temporary extension or phasing the subsidies out rather than full expiration, to avoid negative fallout in the 2026 mid-term elections.

- **340B Drug Pricing Reform:** We believe that ongoing litigation between **Johnson and Johnson** (JNJ) and **Health Resources & Services Administration** (HRSA) over rebate duplication for products that receive a maximum fair price in Medicare will put pressure on Congress to reopen the statute. This is especially true given new Majority Leader John Thune (R-SD) has led the 340B Bipartisan Working Group and Senate Health, Education, Labor and Pensions (HELP) Committee Chairman Bill Cassidy (R-L) has requested information from covered entities (i.e., **hospitals**) on the use of 340B revenue as part of a broader investigation into potential abuses of the program. Changes we would expect the GOP to make to the program would likely be **positive** for drug manufacturers [**Bristol Myers Squibb** (BMY), **Merck** (MRK) and **AstraZeneca** (AZN)] but **negative** for covered entities: eligible hospitals, pharmacy benefit managers (PBMs) [**CVS** (CVS), **Cigna** (CI) and **UnitedHealth Group** (UNH)], wholesalers [**AmerisourceBergen** (COR), **Cardinal Health** (CAH), and **McKesson Corporation** (MCK)], and 340B-eligible dispensers such as 340B contract pharmacies [**Walgreens** (WBA), **Walmart** (WMT)] if Medicare is removed as a payer from the program.

- **Medicare Site Neutral Payments:** Most likely site neutral reimbursement reform will be based on a patient's clinical complexity or health status. Moreover, we would expect a consolidation of existing payment systems – raising Ambulatory Surgical Center (ASCs) reimbursement but lowering hospital

outpatient reimbursement – to bring payments closer in-line with each other. In 2023, a variety of bills were scored by the CBO, with savings ranging from $5 billion to $100 billion over 10 years. We would expect hospitals [**HCA** (HCA), **Tenet** (THC), **Community** (CYH), private **LifePoint, municipally-backed hospitals**] to see a decrease in Medicare reimbursement and ambulatory surgery centers (ASCs) [**Surgery Partners** (SGRY), **Tenet, HCA, UnitedHealth's** (UNH) Surgical Care Affiliates unit, and private **Envision**] to see an increase. Although we view site-neutral payment reform as a priority of incoming Senate HELP Chairman Cassidy, it is most likely to be a slow burn for enactment, with legislation likely coming together in 2H25.

- **Health Care REITS:** Our base case remains that Health Care REIT reform is likely to generate significant bipartisan support, with scrutiny intensifying in 2025 under Chairman Cassidy. Potentially, such reform could follow a similar trajectory of the No Surprises Act to protect patients from harm by setting new guardrails in lease arrangements between hospitals and REITs. We would anticipate that representatives from **Medical Trust Properties** (MPW) could be called before Congress. Furthermore, with Steward Hospital CEO Ralph Del La Torre being held in criminal contempt over mismanagement of his hospital system, we expect he will face legal consequences even with the change in administration. We also expect states to start introducing and likely enacting legislation in 2025 to set contracting requirements between hospitals and their landlords.

Our base case is that significant health care reform will be addressed in 2025, driven largely by the expiration of ACA enhanced subsidies. We believe that Congress, in the lame duck session, will pass a year-end spending deal to reduce funding cuts to Medicaid Disproportionate Share Hospitals (DSH) and Medicare Physician Fee Schedule (PFS). We believe this will be **positive** for physician staffing firms [**RadNet** (RDNT), **Pediatrix Medical Group** (MD), **US Physical Therapy** (USPH), and privately held **Radiology Partners**, **US Anesthesiology**, and **US Physical Therapy**] as we would expect Congress to cut the reduce aggregate payment for CY2025 from 2.8 percent to at least 1.4 percent. We also believe that Congress will increase annual funding for community health centers and continue Medicare telehealth flexibilities. Additionally, around 30 health care extenders are up for renewal, ranging from ground ambulance add-on payments to clinical laboratory fee schedule cuts.

We believe that the minimum nurse staffing rule, scored as costing the government $22 billion, will be the main payfor to prevent funding cuts and provide further spending flexibility, alongside a collection of smaller provisions likely including limited drug manufacturer patent reform and delaying the oral-only end-stage renal disease (ESRD) bundle. If the rule is repealed, we believe that it would be a **positive** for nursing homes [**Ensign** (ENSG), **Brookdale**, private **Providence Group**] and their post-acute care REIT landlords [**Omega** (OHI), **Sabra** (SBRA), **LTC Properties** (LTC), **CareTrust REIT** (CTRE), **Ventas** (VTR), **Welltower** (WELL)] which would eliminate additional costs, estimated to be $6.5 billion annually, to comply with the mandate. Moreover, we believe that delaying implementation of the oral-only ESRD bundle until 2027 will be positive for **Sanofi** (SNY) and **Ardelyx** (ARDX), especially now that CMS has projected ESRD bundle payments will increase by $180 million, with $40 million specifically needed to cover the addition of phosphate binders to the oral-only bundle in the CY2025 ESRD final rate rule.

We do not expect that President Biden would veto a year-end spending deal that repealed the nurse staffing rule. Beyond the current permanent mental and behavioral health extensions, we anticipate a robust discussion on whether it is most appropriate to continue to maintain telehealth flexibilities temporarily until Congress further investigates fraud and overutilization.

Year End Health Care Provisions to Watch

The Fate of Pharmaceuticals

Our base case remains that it is unlikely that any legislation on pricing transparency will move beyond the *Lower Cost Transparency Act* as part of a health care year-end payfor. We believe PBMs will have a short respite from meaningful legislation until the next Congress. A positive for the three largest vertically integrated PBMs [**OptumRx** (UNH), **CVS** (CVS), **Express Scripts** (CI)].

A year end package will likely be somewhat **negative** for large drug manufacturers [**Johnson & Johnson** (JNJ), **AbbVie** (ABBV) **Merck** (MRK), **AstraZeneca** (AZN), **Pfizer** (PFE), **Roche** (ROG.SW)] due to proposed patent reforms. The Promoting and Respecting Economically Vital American Innovation Leadership (PREVAIL) Act, which updates the mechanism the Patent Trial and Appeal Board (PTAB) uses to adjudicate patent validity, and the Patent Eligibility Restoration Act (PERA), which eliminates all judicially-created exemptions to U.S. patent eligibility law, have both been delayed. We expect a positive outlook for their reconsideration in the 119th Congress resulting in difficulties challenging patent thickets for **Sandoz** (SDZ), **Teva** (TEVA), **Biocon Biologics** (BIOCON) and **Amneal Pharmaceuticals** (AMRX).

The BIOSECURE Act, which would restrict U.S. biotechnology entities from working with named companies of concern from countries deemed as adversaries [**WuXi AppTec, BGI Group, MGI, Complete Genomics, WuXi Biologics**], could be attached to slow-moving defense budget legislation, which Congress also must pass before the end of the year. The bill now prohibits such contracting if the services of concern are used by an executive agency or funded by federal loans or grants (only the House version clarifies reimbursement for prescription drugs or medical devices covered by Medicare or Medicaid will not be subject to the bill). Although met initially with strong bipartisan interest, there have been dwindling pathways forward and it is unclear if House Speaker Mike Johnson (R-LA) will renew the temporary House committee on China that the bill came out of next year.

To address the economic drivers of prescription drug shortages, the Senate Finance Committee will likely revisit efforts to ensure the availability of sterile generic by implementing a new Medicare Drug Shortage Prevention and Mitigation Program, which financially incentivizes hospitals, group-purchasing organizations, and others [**Cardinal Health, McKesson**] to prioritize the quality and reliability of supply chains in prescription drug-purchasing decision.

Finally, rare disease advocates and their companies [**Ultragenyx Pharmaceuticals** (RARE), **Pfizer, Alexion Pharmaceuticals** (AZN)] have feared the expiration of the Rare Pediatric Disease Priority Review Vouchers

(PRV). Originally set to expire September 30, 2024, Congress punted to a December 20 expiration date. Under this program, companies that develop novel therapies for rare pediatric diseases can be awarded a PRV, which allows a sponsor to obtain priority review for a New Drug Application (NDA) or Biologic License Application (BLA) that would otherwise not qualify for priority review; it can also be sold or transferred to another manufacturer to obtain a priority review for their product. We expect a temporary continuation of this program with additional scrutiny around guardrails of who a company can sell their PRV to.