From Private Equity Ownership to PBMs and Drug Pricing Congress Scrutinizes the Health Care Industry

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- Congress is taking a closer look at business practices in the health care sector and considering bipartisan reforms in light of increasing consolidation and its perceived affects on patient access and affordability.
- Various congressional proposals (i) would impose new disclosure requirements on a range of health care entities related to ownership by certain private equity funds, venture capital firms and other asset managers, and (ii) would create new non-compliance penalties. Expect this transparency requirement to follow a natural progression in the medium-term into comparative health care outcomes analysis and potential long-term policy changes based on that analysis.
- The concerns around consolidation and vertical integration in health care include the business practices of PBMs, which is a leading area of focus by committees in both the House and Senate.
- The lack of certainty for commercial viability of pharmaceutical products continues to be in flux as the pharmaceutical industry navigates a highly dynamic and actively evolving landscape with CMS moving forward with the implementation of the price-setting provisions of the IRA, and issuing revised guidance at the end of June 2023. To date, four lawsuits have been filed that challenge the legality and constitutionality of the IRA's drug price-setting provisions, adding further uncertainty regarding these unprecedented reforms. Moreover, Congress may legislate further drug pricing reforms, and CMS may take further administrative action, adding additional uncertainty for industry stakeholders.
- Stakeholders must continue to watch closely for further developments from Congress and the Biden administration, including how the focus on private capital in health care may evolve alongside potential reforms aimed at increasing transparency and competition across the sector.

Background

The first six months of the 118th Congress have been an active stretch for the House and Senate committees with jurisdiction over health care issues. Legislative activity has spanned the health care ecosystem, ranging from hearings to legislative mark-ups. A key theme transcending much of this bicameral, bipartisan activity is the examination of consolidation in health care, with a particular focus on the role of pharmacy benefit managers (PBMs) in the pharmaceutical supply chain, as well as a renewed interest in increasing transparency in health care.

Certain aspects of this activity continue to focus on private equity funds, growth funds, venture capital firms and other asset managers, including legislative proposals that would establish new reporting requirements related to health care ownership. These legislative reforms are not being considered in a vacuum: health care stakeholders continue to navigate an actively evolving landscape with the implementation of the drug pricing provisions included in the **Inflation Reduction Act** (IRA), the impacts of which are not confined to the pharmaceutical

industry. All of these developments continue to impact strategies for investment in health care and the life sciences. This Alert highlights a few key areas that are worthy of deeper consideration.

Key House Development: Energy and Commerce Committee Advances the PATIENT Act

In May 2023, the House Energy and Commerce Committee approved H.R. 3561, the Promoting Access to Treatments and Increasing Extremely Needed Transparency Act of 2023 (the "PATIENT Act") by a unanimous, bipartisan vote of 49-0. Section 104 of this legislation will require certain hospitals, certain ambulatory surgical centers, independent freestanding emergency departments, certain larger physician practices and physician practices owned by a hospital, a health plan, a private equity fund, a growth fund, a venture capital firm or similar asset manager, to file annual reports to the Secretary of Health and Human Services (HHS) regarding data on ownership, mergers & acquisitions (e.g. add-on acquisitions) and changes in ownership for the previous year. Whether or not an ownership interest triggers this requirement depends on whether the entity qualifies as a "person with an ownership or control interest" as specifically definited in section 1124(a)(3) of the Social Security Act. Each such entity would also be required to submit the name, address and business structure of its "parent company" as of the date of the submission of the report, as well as any other information with respect to ownership as determined by the Secretary.

Hospitals would be required additionally to report the hospital's tax status, the average debt-to-earnings ratio, information regarding incurred debt and information with respect to real estate leases and purchases for property used, or intended to be used, to support the provision of health care services, among other factors.

Reporting would begin January 1, 2025, and much of this information would become publicly available beginning in 2027, as the Secretary of HHS would be required to post this information (and analysis related to horizontal and vertical consolidation) received through these reports on its website. The Secretary is also charged with conducting audits to ensure compliance with the new reporting requirements. Notably, H.R. 3561 would also establish hefty penalties (civil monetary penalties up to $5 million) for failure to report or for submission of false information in a report.

With an increased focus on transparency, the PATIENT Act also includes two site-neutral payment policies affecting services provided at hospital outpatient departments and physician offices. The legislation would implement site-neutral payment policies under Medicare for drugs administered in off-campus hospital outpatient departments, which is estimated to save the government $3 billion over 10 years. These monies could be used to pay for stopping the Medicaid Disproportionate Share Hospital (DSH) cuts in Fiscal Year (FY) 2023-25. In addition, the PATIENT Act would further require that providers include a unique identification number for its services and that hospitals submit additional attestations to the Centers for Medicare & Medicaid Services (CMS) for each of their outpatient departments.

While there is not yet a Senate companion for the PATIENT Act, the overwhelming support for H.R. 3561 coming out of the recent House Energy and Commerce Committee mark-up underscores the bipartisan interest in considering reforms that would increase transparency in the ownership of health care entities participating in the Medicare program. The interest in these issues is unlikely to dissipate any time soon.

Senate Considerations: PBMs Plus

Each of the Senate Health, Education, Labor and Pensions (HELP), Senate Finance and Senate Commerce Committees is also considering various health care consolidation and transparency issues. As part of the Senate HELP Committee's focus on drug pricing, the Committee had PBMs testify before the Committee as part of its consideration of legislation related to PBMs. Key aspects of the hearing focused on exploring the vertical integration of PBMs with insurers, pharmacy chains and others, as well as on the flow of rebate dollars from the PBMs to the insurers who are their "customers." On the heels of a series of drug pricing related hearings, the

Senate HELP Committee approved S. 1339, the Pharmacy Benefit Manager Reform Act. This bipartisan legislation would increase oversight of pharmacy benefit management services with respect to group health plans and health insurance coverage.

The Senate Finance Committee has also been looking at PBM reforms. Earlier this year, Senate Finance Committee Chair Ron Wyden (D-OR) and Ranking Member Mike Crapo (R-ID) released a legislative framework to address PBMs. More recently, the Committee Chair and Ranking Member, along with Sens. Bob Menendez (D-N.J.), Marsha Blackburn (R-TN), Jon Tester (D-MT) and Roger Marshall (R-KS), introduced the Patients Before Middlemen Act to delink the compensation of PBMs from drug price and utilization.

The Finance Committee has also been examining consolidation and transparency in other areas of health care. Last month, the Committee held a hearing entitled "Consolidation and Corporate Ownership in Health Care: Trends and Impacts on Access, Quality, and Costs." The hearing included discussion regarding the increasing trends and impacts of provider integration between hospitals and physicians, increasing concentration in insurance and physician markets, and the role of PBMs and private capital in health care, including private equity and other asset manager investment in the health sector. It is clear that Congress is keen on examining transparency, competition and consolidation across the health care sector and stakeholders should watch to see how the focus on private capital in health care plays out.

In March 2023, the Senate Commerce Committee advanced the Pharmacy Benefit Manager Transparency Act (S. 127), introduced by Sens. Maria Cantwell (D-WA), Chair of the Commerce Committee, and Chuck Grassley (R-IA). This bipartisan bill would prohibit PBMs from engaging in certain practices, including charging a health insurance plan an amount that is different than the amount the PBM reimburses the pharmacy—so-called "spread pricing."

The bill also includes provisions prohibiting clawing back reimbursement payments, increasing fees or lowering reimbursement to pharmacies to offset changes to federally funded health plans, unless certain price concessions, or discounts, and disclosures are provided with respect to PBM services. The bill also includes new requirements for PBMs to provide certain information to the Federal Trade Commission (FTC), authorizes the FTC and state attorneys general to enforce provisions of the bill, and requires the FTC to report to Congress on PBM practices. Additionally, the bill directs the Government Accountability Office (GAO) to study and report on PBMs, including providing recommendations for legislative action to lower the cost of prescription drugs, improve the pharmaceutical supply chain, improve competition and provide transparency, in pharmacy benefit management. Notably, the bill also establishes new penalties for noncompliance in addition to those already applicable under the Federal Trade Commission Act.

In parallel with these efforts, senators from both aisles continue to urge the FTC to complete its ongoing study into the practices of PBMs, which, according to FTC, "operate with little to no transparency."[1] In June 2022, FTC had announced that it was launching a major inquiry into the "Presciption Drug Middlemen Industry", meaning, the six largest PBMs. FTC says it will be looking into the impact of vertical integration of PBMs and insurers, prescription drug mail order services, and specialty pharmacies. Moreover, FTC's view is that PBMs have "enormous influence" on which drugs are prescribed and which pharmacies are used by patients, and deploy "highly complicated, opaque contractual relationships that are difficult or impossible to understand for patients." As a result, FTC has issued compulsory orders to the PBMs, under Section 6(b) of the Federal Trade Commission Act.

Rather than commit to completing that year-old inquiry, instead, on June 8, 2023, the FTC expanded its study into the impact of PBM practices on the cost and accessibility of prescription drugs by seeking information from three Group Purchasing Organizations (GPOs), which are intermediaries between health care providers, on the one hand, and manufacturers, distributors and other vendors, on the other hand, that pool purchasing volume to negotiate lower prices for PBMs and health care providers. While results from the FTC's inquiry into PBMs will

undoubtedly influence the direction of any legislation aimed at regulating PBMs, the expanded scope of the FTC's investigation suggests that it may be some time before the FTC reports any conclusions.

Site Neutral Payment Provisions

As previously discussed, the House Energy and Commerce Committee, despite objections from the hospital industry, did approve narrow site-neutral policies in the PATIENT Act. However, it is important to note that prior to the mark-up of that bill, the Committee put forward other site-neutral legislation for consideration. First, the "Grandfathered" bill would build off the Bipartisan Budget Act (BBA) of 2015's site-neutral policy, by requiring that all services provided in off-campus outpatient departments would be paid at the same rate as other outpatient sites of services, such as physician offices. The policy would be applied to the "grandfathered" off-campus outpatient hospital departments that were in existence prior to 2015, and that had been exempted from the site neutral reimbursement cuts under the BBA of 2015. This proposal is estimated to save the government over $31 billion over 10 years.

Second, in its June 2023 Report to Congress, the Medicare Payment Advisory Commission (MedPAC) included a site-neutral proposal for consideration. This proposal would establish site neutral payments for certain low-acuity services that CMS deemed safe to perform in multiple care settings, including ambulatory surgery centers (ASCs). Safety net hospitals would be limited to a 4.1% Medicare revenue reduction under this proposal, providing the Secretary with discretion to lessen the amount. This proposal has been publicly reported as estimated to save the government $180 billion over 10 years.

Both proposals were ultimately not included in the Committee's final transparency package, but it was clear that Members on both sides of the aisle, including Chair Cathy McMorris Rodgers (R-WA), were supportive of moving forward more expansive site-neutral policies. Chair Rodgers urged hospitals to work with Congress on these proposals.

In addition, in early June of this year, Sens. Mike Braun (R-IN), Maggie Hassan (D-NH) and John Kennedy (R-LA) introduced the Site-based Invoicing and Transparency Enhancement Act or the SITE Act (S. 1869). The bill ends the BBA of 2015 exemption and reduces payment for certain covered services furnished by off-campus outpatient departments by 30%. The bill mandates that each off-campus outpatient department of a provider will be required to have a separate unique health identifier. It also outlines billing requirements for off-campus outpatient departments, asserting that claims for services must include the unique health identifier and be on a specified form. The bill utilizes savings from the site-neutral policy for the creation of a Graduate Nursing Education Program that would provide hospitals with payments for nurse training costs.

Even with the site-neutral payment reforms under the BBA of 2015, many lawmakers continue to believe that health systems have been incentivized to expand their outpatient offerings in order to obtain higher reimbursement, leading to increased consolidation of hospital systems, ASCs and independent physician offices. On the other hand, hospitals argue that certain patients require a higher acuity setting for more complex services and that overall hospitals have higher overhead costs to consider.

Site-neutral policy proposals are not going away. In just the coming month, the Senate Finance Committee and the House Ways and Means Committee are expected to consider site-neutral legislation ahead of the August recess.

Drug Pricing Dynamics

Like all stakeholders in the life sciences community, private equity funds, growth equity funds, venture capital firms and other similar asset managers in this space should be closely watching to see how the implementation of the drug pricing reforms included in the IRA unfold. The IRA represents sweeping reforms to the Medicare

program with enactment of the Medicare Part D benefit redesign, inflation rebates for Part B and Part D drugs, and a new Medicare Drug Pricing Negotiation Program that empowers the Secretary of HHS to set prices for certain drugs that are reimbursed under Medicare. While CMS has released guidance on the implementation of the Negotiation Program, significant questions remain regarding aspects of the Negotiation Program. Stakeholders are closely watching to see how CMS moves forward to inform strategic decisions around the development and commercialization of drug products.

As recently as June 30, 2023, CMS released revised guidance on the drug pricing program, including changes to the way CMS will verify drugs that are exempt from price controls due to generic competition, "orphan drug" designation, and patent litigation (in the case of biologics only as to a special two-year delay procedure). The new guidance also makes several important procedural changes affecting confidentiality of negotiations, challenges to CMS's price calculations and some temporary delays in implementation of price discounts in 2026 as to certain hospitals, physicians and other providers. These and other adjustments to the CMS approach will need to be factored into any assessment of the IRA's potential impact on the commercial viability of a drug or biologic, on a case-by-case basis.

Further, four lawsuits challenging the legality and constitutionality of the Negotiation Program have already been filed in the federal courts and more are likely on the way. This has only added to the uncertainties surrounding the implementation of the IRA's drug pricing reforms and increased the complex dynamics of the considerations for those impacted by the IRA.

What's Next?

While there has been a tremendous amount of activity across the House and Senate Committees of jurisdiction for health care in the first six months of this year, it remains to be seen if and how the two Chambers might come together to advance the health bills they have considered within their respective committees. Despite these uncertainties, it is clear that there is bipartisan, bicameral interest in a range of health care issues related to consolidation, transparency and ownership of health care entities, including private equity, growth equity and venture capital funds in the health care sector. No issue better underscores this point than the focus on PBMs by numerous Committees in both the House and Senate. Cast against this congressional backdrop, the life sciences community continues to absorb the impacts and considerations of IRA's drug pricing reforms and navigate a dynamic landscape on these evolving fronts. Stakeholders in this space should continue to watch closely to see how proposals by Congress, MedPAC and the Biden administration might further alter the path and strategies for researching, developing and bringing safe and effective therapies to market on behalf of patients.

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[1] Sens. Chuck Grassley (R-Iowa), Cindy Hyde-Smith (R-Miss.), James Lankford (R-Okla.), Marsha Blackburn (R-Tenn.), Jerry Moran (R-Kan.) and Thom Tillis (R-N.C.), Letter to FTC Chair Lina Khan, Oct. 7, 2022.