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SPOTLIGHT REPORT

January 12, 2023

Healthcare Policy Outlook for 2023

What's Happening: For Democrats, 2022 was all about determining what was politically possible in terms of new healthcare legislation. It began with dreams of expanding Medicare to hearing and dental coverage and mandating Medicare negotiations for all of the most expensive prescription drugs. In the end though, most of these policy dreams were a bridge too far, although a number of substantial policies still passed into law. The implementation of these legislative achievements and continued advancement of other long-term Biden administration regulatory priorities will be the focus of 2023, particularly now that Republicans control the House of Representatives.

Why It Matters: For investors, this shift from trying to effectuate sweeping legislative changes to implementing regulations means that there is less uncertainty regarding policy outcomes. As an example, we can safely say that certain big changes, such as an expansion of Medicare or repeal of elements of the Affordable Care Act, will categorically not happen this year or for the remainder of President Biden's current term due to the political dynamics of divided government. This will mean relatively small changes in some sub-sectors, such as for managed care insurers, but in others where there is a new regulatory structure, such as for prescription drugs, the coming year will be critically important for knowing the disparate impact of the new rules on various companies as well as understanding the environment going forward. **Each sub-sector of healthcare will have to be examined for its own unique policy risk or opportunity.**

What's Next: We expect that the Centers for Medicare and Medicaid Services (CMS) will do all that it can to ensure that progressive regulatory priorities are proposed and, if possible, finalized by the end of this year or early 2024 so that they can avoid the risk of these rules being repealed via the Congressional Review Act, should Republicans sweep back into power in 2025 and gain unified control of government. There is also a political element in play with timing, particularly if Biden's eventual opponent is someone other than former President Trump. The White House will want to run its re-election campaign based, at least in part, on legislative and regulatory achievements, so it will need to have consumers feeling the tangible benefits of as many of those policies as possible by the time they go to the ballot box in the fall of 2024.

2022 Legislative Achievements

Inflation Reduction Act: The Inflation Reduction Act contained the biggest legislative change in healthcare since the Affordable Care Act (ACA) – the ability for Medicare to negotiate the prices it will pay for prescription drugs with their manufacturers. It also included mandatory inflation rebates paid to Medicare for manufacturers that raised a product's prices faster than inflation, a $2,000 per year cap on senior citizen out-of-pocket spending in Medicare Part D starting in 2025, and redesign of the financing of Part D, a $35 per month cap on insulin prices in Medicare Part D starting in 2023, and continued support through 2025 for expanded subsidies to purchase health insurance via the ACA, among other policies.

Omnibus FY23 Appropriations Act: The year-end omnibus package contained several important healthcare provisions that will make an impact on market participants in 2023 and beyond. First is that Medicare physician fee payments were altered to reduce the planned cut by 2.5 percent for 2023 and 1.25 percent for 2024, leaving providers with a net two percent cut for 2023. This means that there are still going to be reduced payments for this year and next, but not as bad as was planned. There was also a waiver of statutory PAYGO cuts for 2023 and 2024 that would have added another four percent cut to providers.

Telehealth companies received additional certainty as Medicare's expanded access was continued for two more years through 2024. Also included in this extension was the ability to exempt telehealth from the deductible in high-deductible health plans paired with Health Savings Accounts.

For Medicaid, there were three substantial changes that were all linked. The main policy change that will impact investors is that state Medicaid eligibility redeterminations are now allowed to begin in April 2023 which will result in significant churn in the population receiving this coverage. States have been under orders to maintain their rolls continuously in exchange for the 2020 pandemic relief boost of the Federal Medical Assistance Program rate by 6.2 percent.

In effect, the government had strongly incentivized states to expand their rolls to take on more Medicaid patients with the additional funds, but did not let them reevaluate their current status to see if they remained eligible based on income. Originally, the end of the Covid-based public health emergency was the trigger for allowing redeterminations, but this ever-shifting date created problems for state Medicaid agencies. Now there is a date certain when this churn will begin and states can plan on how to best shift the majority of those they are kicking off the rolls onto ACA plans.

In exchange for this date certain, Democrats were able to use the "savings" to extend the Children's Health Insurance Program (CHIP) through FY29 and have continuous coverage for women during their post-partum period and 12 months for children enrolled under CHIP.

2023 Regulations by Sub-sector

Prescription Drug Manufacturers: CMS is in the process of setting up a 95-person negotiating office, the Medicare Drug Rebate and Negotiations Group, which has been charged with issuing the new guidance that will implement the drug reforms in the IRA. Just days ago, CMS Administrator Chiquita Brooks-LaSure released a roadmap for how the agency intends to implement the law over the coming year. CMS also issued a memo that gave additional details on the stakeholder feedback it is asking for as well as the guidance it intends to issue in lieu of a more formalized notice and comment rulemaking.

There are many key takeaways from this announcement including the fact that the first two tranches of drugs for negotiation will only come from Part D and NOT Part B; we will know which 10 drugs are selected on September 1st, 2023; and we will know the final prices for them on September 1st, 2024, although companies will have been "negotiating" with CMS since February 1st, 2024 and there is every chance that the price debate leaks to the public.

Key dates that will be useful to investors include the following:

- Winter 2023 -- comment period for for small biotech company exemptions published;
- **June 1st, 2022 to May 31st, 2023 -- period for total expenditure calculations which will be used to determine which drugs are selected for negotiated prices in 2026;**
- Summer 2023 -- comment requests for negotiation and counter offer and data elements are released;
- **September 1st, 2023 -- CMS will publish its list of 10 Part D drugs for 2026 price negotiation;**
- **February 1st, 2024 -- CMS will send initial price offers; and**
- **September 1st, 2024 -- CMS will publish the maximum fair prices they will pay starting on January 1st, 2026.**

In the future, CMS will keep the original 10 drugs at the lower negotiated prices and then add 15 more Part D drugs in 2027. In 2028, CMS can add Part B drugs to the mix, with 15 new products, and 20 more Part B or D drugs in each year thereafter.

Also of note is that insulin for seniors on Medicare is now capped at $35 per month with no deductible and if drug prices for a product increases faster than inflation (across all payors), then the manufacturers must pay a rebate to Medicare. The period of time for calculating this rebate commenced on October 1st, 2022 for Part D and January 1st, 2023 for Part B.

All of these changes will be meaningful for the companies that are impacted, but if a manufacturer is not included in the initial 10 drugs and has not increased prices more than inflation, then there will be no substantial change in government policy to reduce revenue in 2023 or 2024. There is every risk though that a new company or product will be included in the future, requiring ongoing analysis.

Hospitals: 2023 is going to be a year of some change and uncertainty for hospitals, but in policy terms it will be better than it could have been. First, in the FY23 Omnibus Appropriations Act discussed above, the Medicare fee cuts to providers were at least partially ameliorated and the PAYGO cuts (four percent) were avoided entirely. **This means that hospitals will now have certainty regarding payments from Medicare for 2023 and 2024.** We do not expect that there will be any new legislation or regulatory announcements that will reduce or increase physician payments for CY23.

Next, in terms of the number of uninsured, this year has been very good in terms of enrollment in ACA plans, with over 16 million people enrolled as of January 11th, which is an increase of 13 percent or 3 million new lives. We do not expect any legislative changes to the ACA that would decrease the number of insured under this program and the total number may still go up before open enrollment closes.

For Medicaid, the end of the maintenance of effort rules that were included in the omnibus legislation will create the largest amount of uncertainty for hospitals, particularly if they are located in states that will be zealously looking to trim their Medicaid rolls without also providing resources and assistance for many of those who are "trimmed" to access the ACA exchange plans.

The redeterminations will begin in April 2023 and investors in hospitals should determine the geographic coverage of their specific company and then use the coming months to try to determine the plans that states and hospitals themselves have for this process. An additional way to gauge the risk of this policy shift is to determine the current "mix" of payor (private insurance, Medicare, Medicaid, etc.) for a hospital company and then use that information, coupled with state data, to evaluate the impact of any changes.

A separate, but still relevant, policy change is in the antitrust space. The Federal Trade Commission (FTC) has already blocked several hospital merger transactions and we expect that it will challenge even more in the next two years with the bias of the agency against allowing any additional consolidation in this sub-sector.

Health Insurers: Even more so than hospitals, **health insurers will benefit from the knowledge that there will not be any new substantial changes in payment policy or eligibility standards for the ACA, Medicare Advantage, or Medicaid in the near term**. There is always controversy over annually set Medicare Advantage rates and there could be a new demonstration from the Centers for Medicare and Medicaid Innovation that focuses on value-based care, but we do not expect any new legislation that would be positive or negative, nor do we expect any new proposals that would restrict coverage from the Biden administration.

The only policy changes that will reduce the number of lives covered by insurers will be in state managed care Medicaid plans which will see a decrease due to the aforementioned redeterminations, although many of these people could be picked up by ACA plans mid-year.

Telehealth: Also in the FY23 omnibus package, **telehealth was given some breathing space to continue under the status quo until the end of 2024**. We expect that companies will use this time to continue to build their case that they do not promote fraud and that they can create better health outcomes and that these outcomes are consistent across race and class. We do not expect any new legislation or regulation in this sub-sector until near the end of this extension.

Pharmacy Benefit Managers (PBMs): **Unlike many of the other sub-sectors of healthcare, PBMs remain squarely in the spotlight of many members of Congress and the Biden administration's antitrust regulators.** On the legislative front, several bills that would have further regulated the business practices of PBMs were not included in the end of year omnibus, but their sponsors are highly unlikely to drop their interest in reining in the sector.

We expect that there will be significant headline risk from congressional hearings, investigations, reports, and even new legislation. We do not believe that any of the legislation is likely to pass in a divided Congress, which means that legislative risk will remain low, though not entirely impossible.

Instead, the biggest risk is regulatory and comes from the FTC. There has been more activity by the FTC looking into PBMs and their business model than nearly any other sub-sector of healthcare, including a unanimous vote by the commission to pursue an enforcement policy statement, an ongoing market inquiry study, and an earlier request for public comment that resulted in one of the largest number of public comments ever (1,200 individual comments from more than 24,000 parties) for an issue before the FTC.

While the FTC has been aggressive in certain areas in advancing novel policies, it has been more restrained in healthcare than many expected, at least thus far. We expect that the FTC under Chair Lina Khan will look to use its ability to scrutinize any deal with a major PBM, such as the rumored **CVS Health (CVS)/Oak Street Health (OSH)** transaction, as a vehicle to also examine the size, scope, and business model of CVS Health. This is separate from any decision to bring an enforcement action more broadly against the biggest players based on the results of the study, which we expect to see in 2023.

At a 2022 event before community pharmacists, Khan said, "Specifically, we noted our intention to examine the effects of the rebates that drug manufacturers pay to PBMs. We've heard concerns that these rebates might function as 'kickbacks,' and that drug manufacturers may effectively be paying PBMs to exclude cheaper drugs—like generics and biosimilars—from their formularies, which in practice means that fewer patients have access to more affordable medicines, and they're instead left paying more money, or not being able to afford medicine at all."

Khan went on to criticize the political choices that led to a company like CVS Health becoming so large and vertically integrated. She said, "First, it's so critical to remember

that the current structure of the market, the current structure of the industry, and the types of business practices that occur are not inevitable or some inexorable force of nature. These features of our current system are the result of policy choices and legal decisions that were made by people, including officials at the FTC and Antitrust Division, but also public officials who are elected and directly accountable to you. It was policy choices that permitted PBMs to merge with one another, creating a more concentrated market. It was policy choices that permitted PBMs to vertically merge with health insurance companies on one side and specialty and retail pharmacies on the other side, which many have noted can create a sharp conflict of interest."

This critical tone and multiple policy initiatives in this area leads us to believe that Khan has substantial animus towards CVS Health and other large PBMs (CVS Health also owns major insurer Aetna) and would not lose an opportunity either to try to block such a transaction or use it to change the business practices of CVS Caremark, its PBM, particularly regarding its core business of negotiating rebates from prescription drug manufacturers. As Khan said in her public remarks preceding the vote on the enforcement policy statement, "I am committed to ensuring that the FTC is bringing all our tools to bear on unlawful business practices that may be resulting in Americans paying higher prices for medicines."

Whether the FTC is successful or not in any of its intentions towards PBMs remains an open question, but the risk of action from this highly motivated regulator will be an important aspect of analyzing any company in this sub-sector.

Nursing Homes: The Biden administration in 2022 began a multi-pronged push to reform the nursing home sector. This includes the goal of attempting to "improve the safety and quality of nursing home care, hold nursing homes accountable for the care they provide, and make the quality of care and facility ownership more transparent so that potential residents and their loved ones can make informed decisions about care."

In 2023, investors should stay focused on two aspects of that regulatory agenda that will have a financial impact versus the other aspects that are designed to generate political headlines. The first is a study that is supposed to be released in the first half of the year that will likely shed some light on the administration's plans regarding mandatory registered nurse staffing ratios for nursing homes. The second, is the Skilled-Nursing Facility (Nursing Home) CY24 payment rule itself, which will contain the minimum staffing requirement provisions and the financial penalties for not meeting these requirements. The White House fact sheet ends the section on staffing requirements by saying, "Nursing homes will be held accountable if they fail to meet this standard." There is no definition of "held accountable" in this section, but later there is discussion of financial penalties for poor performance, which presumably would include violation of staffing requirements.

This policy is the most important for nursing home investors because it can be promulgated without Congress and because it would increase costs for nursing homes, potentially significantly. At the same time as costs are likely to increase, there is not any proposal that Medicaid, the largest payor for nursing home

residents, increase its reimbursement rates. This means that facilities will have to charge the few patients paying out-of-pocket more, cut costs in other areas, or will see their margins reduced.

The study alone could spook investors and nursing home operators due to the increased costs that it would require. Despite this headline risk, we are confident that this will not ultimately result in materially adverse consequences for nursing homes. The biggest reason that this forthcoming rule is not going to cause closures on its own is that there simply are not enough active registered nurses to dramatically increase headcount at nursing homes as well as maintain them in better paid hospital settings.

During the Covid-19 epidemic, there was a large shift away from nursing in general and it takes years before educational choices of a new generation of nursing students can be reflected in an increased number of potential staff with those specific qualifications. Registered nurse licenses take between two to four years of education and training, depending on the program.

Therefore, we believe any final rule will have to have some sort of waiver or accept proof that a nursing home is attempting to increase staff numbers – the Biden administration does not want to have multiple nursing homes be forced to close in the run-up to the 2024 election due to a policy that was meant to make voters' loved ones safer.

In terms of payments to nursing homes, the fixed amount of money that the institutions receive per patient from Medicaid, as the largest payor, is also one of the biggest hindrances in attracting more nurses into the field compared to other areas of healthcare. The Biden administration's proposal does not include any increase in what Medicaid pays to nursing homes and we do not expect that there will be any legislative component to this regulatory agenda.