

# 2024 Health Care Preview



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## *Introduction*

Make no mistake – we are headed toward the silly season.

The 2024 presidential election is well underway at this point. President Joe Biden is seeking re-election against a Republican field currently led by former President Donald Trump.

Before we get fully into election season, there are legislative and regulatory remnants of 2023 that will likely be addressed in early 2024. Congress is adjourning for 2023 with some significant policy questions outstanding. While in years past, Congress has crafted and passed government funding packages that included significant policy riders before the Christmas holiday, Congress has punted most of those issues in the health care space until early 2024. As such, we unplug for the holidays on a bit of a cliffhanger.

Once Congress has kept the government funded and cleared at least some of its outstanding to-do list – how does the 2024 election season impact the year, for health policy watchers?

- *Fewer days of Congress in session* – In election years, Congress typically prefers to be away from Washington, D.C. and back in their respective districts, where they can control the messaging shared with voters. We expect no different this year, with Congress out for the months of August and October.
- *More politically focused policymaking* – Expect the Administration and Congress to focus their efforts on policies that speak to their platforms and avoid policies involving major disruption. Perhaps more relevant to the Administration, which can make changes with the stroke of a pen.
- *Political mud-slinging* – OK, well, maybe this issue isn't unique to election years. However, we do expect the intensity of political finger pointing to escalate, which could hurt efforts to forge bipartisan agreement.
- *Relentless focus on health care from the Administration* – Team Biden clearly sees health care as a winning issue for the President going into 2024. That focus likely means the Administration will remain active on target efforts and messaging throughout the year, perhaps developing new initiatives late into the year.

- *A crazed lame duck session* – We recommend keeping your calendar clear for November and December of 2024. There are already Medicare payment policies that expire at the end of 2024, including telehealth flexibilities and payments for certain Medicare designated hospitals. Congress might also punt on any number of issues that could be dealt with in January until after the 2024 election, leaving two nutty months to address stuff before 2025. Throw in the possibility of an Administration change, and we've got ourselves one heckuva holiday season next year.

The bottom line – there won't be a shortage of health care policy in the news next year, generated either by Congress or the Administration. An issue that touches the pocketbooks of so many Americans will always be in play as we head to the voting booths.

## Congress

### Retrospective

In some respects, 2023 went pretty much how we thought it would. In others, it was quite the surprise. Kudos to Congress for keeping us guessing.

In our 2023 preview, we identified four themes we expected to see:

- Gridlock
- High-stakes negotiations
- Oversight
- Bipartisan work

**Gridlock** was, in many ways, a silent presence throughout the year. The House and Senate advanced several legislative priorities through the Committee process – many on a bipartisan basis – and in the case of the House, some even cleared the floor. However, the limited number of moving vehicles scuttled any meaningful discussion of these efforts becoming law.

**High-stakes negotiations** were ever-present throughout the year. In the spring, a high visibility showdown over the federal debt ceiling kept Washington – and the country – on pins and needles until late in the process. In September, Congress averted a government shutdown by mere hours, only to create a new cliff later in the same season.

On the topic of oversight of the executive branch, House Republicans met the moment. House Republicans held a number of oversight hearings targeting the Biden Administration, with a particular focus on how the Administration approached the COVID-19 pandemic.

Both parties were active in **oversight** of the private sector. Newly minted Chairman Bernie Sanders (I-VT) of the Senate Health, Education, Labor, and Pensions (HELP) Committee led the way with high profile hearings and investigations. However, bipartisan investigations into topics including Medicare Advantage prior authorization practices showed the two sides could work together as well.

**Bipartisan activity** was surprisingly robust throughout the year, largely at the expense of the pharmacy benefit manager (PBM) industry. Bipartisan bills have moved through Committees in both chambers that would bring new rules and transparency initiatives to

that industry, as have some other broader transparency initiatives that have passed in the House. Despite the divided Congress, it appears that key policymakers in both parties have found some truly common ground.

### **Looking Ahead**

It's important to look at 2024 as a few distinct periods rather than one continuous year.

#### *Finishing 2023 in 2024 (First quarter)*

In Washington, the holiday season has typically involved a race to the finish, as Congress puts a bow on government funding and other time sensitive items needing action before 2024. In 2020 and 2022, this year-end effort sprung into "Christmas tree bills," which advanced significant chunks of bipartisan health care legislation along the way. However, not so in 2023!

In mid-November, Congress approved a continuing resolution (CR) to fund the government, avoiding a shutdown. For this CR, Congress took a "laddered" approach that created two different funding deadlines for the 12 appropriations bills. The first expiration date is January 19 and includes the Agriculture-FDA, Energy-Water, Military Construction-VA, and Transportation-HUD bills. On February 2, the Commerce-Justice-Science, Defense, Financial Services-General Government, Homeland Security, Interior-Environment, Labor-HHS-Education, Legislative Branch, and State-Foreign Operations bills expire. The package provided short-term extensions to several programs, while allowing others to lapse (see more in the upcoming deadlines section).

The must-do list for January and February on health care isn't super long (funding notwithstanding) – address cuts in the Medicare Physician Fee Schedule, reauthorize community health centers, and delay Medicaid cuts for hospitals to name some of the big issues. Unrelated member priorities – particularly those without a budgetary impact – could also be in the mix for inclusion in the health care title of the January legislation.

However, we also see an opportunity for some bipartisan work to come to fruition in this package. Specifically, both parties and both chambers have worked extensively on reforms of the PBM industry, and other policies focused on price transparency. Particularly given that some of these reforms are projected to save money for the government, we anticipate these policies could be ripe to ride in the package. There is

also a potential for pieces of the Pandemic and All Hazards Preparedness Act and SUPPORT Act to ride.

That's a lot of work to do early in 2024, without the backstop of the holiday recess to drive the activity. Look for a significant chunk of Q1 to be spent on finishing up the work from 2023.



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After 2024 spending is settled Congress will pivot to the 2025 appropriations process. Between the elections, truncated calendar and focus on spending, there will still be opportunities for consideration of other priorities, but people must keep in mind the logistical, timing, and political challenges of 2024.



### *The slog (through election day)*

Once we (quickly and easily with no possible bumps in the road<sup>[1]</sup>) dispense with the remaining business of 2023, it's time to shift to the bulk of the year. Election years are tough periods for getting things done on a bipartisan basis, and next year fits that mold. Look for a lot of Committee activity and floor votes, but not necessarily a lot signed into law.

*[1] This is a joke.*

### *The lame duck (November and December)*

With the elections in the rear view, Congress should have an interesting month of legislating. Lame duck periods are typically a good time for getting bipartisan work over the finish line. However, the results of the elections will also weigh on the approach Congress takes – if one or both chambers of the Congress is set to flip in January, look for leadership to be pragmatic on whether negotiating provisions are better after the start of the new Congress.

As we prepare for 2024, we again look to the themes that percolated in 2023:

### *Gridlock*

Policymakers in the House and Senate are not lacking interest in health care policy. Whether it be on a partisan or bipartisan basis, committee leadership and other thought leaders are itching to move meaningful legislation. The odds of significant legislation passing before the November elections are slim. However, look for many of these artificial barriers to fall during the lame duck session of 2024.

### *High-Stakes Negotiations*

Government funding promises to be an issue throughout 2024. As noted earlier, large chunks of Q1 will be spent on answering the tough question of what Republicans and Democrats can both stomach for 2024. However, the House leadership's new focus on dedicating significant floor time to individual appropriations bills means that the 2025 process will likely kick off not soon after the dust settles from the prior year's fight. In years past, we might have anticipated that Congress would simply punt these issues until the lame duck session. However, recent history suggests that House Republicans may insist on resolving differences in the here and now. The appropriation process, particularly in the House, will be dependent on how Members perceive the conclusion of the FY24 process related to the overall topline number for discretionary spending is set.

### *Oversight*

A sure bet for 2024 – House Republicans will be “liberal” in their oversight of the Biden Administration. With the November elections on the horizon, Republicans will be calling into question the effectiveness of the Biden Administration throughout the year, even during periods when legislative activity subsides. Look for House Republicans to try and muddy the water on the Inflation Reduction Act and the Administration's record on providing insurance coverage.

We anticipate both parties' interest in oversight of the private sector to continue as well. HELP Committee Chairman Sanders has made clear that he will continue to use his post to ask hard questions of the health care industry, at times under the bright lights of hearings. Republicans may join Democrats in tamer, bipartisan efforts, but will also be unafraid to ask hard questions of the industry. We expect more hard questions to be asked of the drug industry and health plans, particularly those participating in Medicare and Medicaid, as both parties have recently developed an interest in prior authorization, denials, and other issues.

### *Bipartisan Work*

Even with the 2024 elections on the horizon, bipartisan work on a number of topics is likely to continue. “Thought leaders” in the health care arena in both the House and the Senate will endeavor to find some common ground on complex issues – for example, dually eligible beneficiaries and reforms to the Physician Fee Schedule. However, the ability to get that work over the finish line may be limited to the lame duck session.



## *The Administration*

### **Retrospective**

The Biden Administration sought to make its mark in 2023, laying out more controversial policies it will seek to finalize in 2024.

Some of those key areas:

- Medicare Advantage – The Centers for Medicare & Medicaid Services (CMS) finalized controversial changes to the risk adjustment model used to calculate payments to Medicare Advantage plans.
- Prescription Drugs – The Administration plowed ahead on implementation of the Inflation Reduction Act, identifying the first ten drugs for negotiation and issuing new guidance on Medicare negotiation, inflation rebates, Part D redesign, and Part D smoothing. However, the Administration also went beyond – CMS proposed changes to the Medicaid Drug Rebate Program and rolled out new models in development at the CMS Innovation Center focused entirely on payment for drugs (including gene therapies and drugs approved under accelerated approval).
- Medicaid – CMS proposed lengthy updates to rules of the road for the Medicaid program, including a new requirement that 80% of payments for direct and personal care go to provider salaries.
- Lab-developed tests – The Food and Drug Administration (FDA) issued a proposed rule at the end of September that would phase out the enforcement discretion the agency has historically exercised over diagnostic tests that are developed and run by laboratories. The proposal would update the medical device regulations to more explicitly apply such authorities to lab-developed tests (LDTs).
- Smoking Rules – FDA has been working on proposed rules to ban menthol in combustible cigarettes and significantly lower nicotine levels for years. While the Unified Agenda predicted these rules being issued in 2023, we anticipate them coming in the first half of 2024.
- Competition policy – The Federal Trade Commission (FTC) and other parts of the government ramped up the Administration’s efforts on “competition” policy, proposing changes to merger policies, a ban on non-compete agreements, and discussions of so-called “march-in rights.”



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With the November elections looming large, the Biden administration will finish major policy initiatives over the next six months. Look for major messaging pushes on prescription drugs and insurance coverage rates, emphasizing the Affordable Care Act.



Helping the cause – 2023 was (arguably) the first post-COVID year. The Administration allowed the COVID-19 Public Health Emergency to end at the beginning of the year, and with it, dozens of temporary policies that had been in place since 2020. No doubt, unwinding all of these policies was time consuming for the executive branch. However, the Administration no longer had to maintain a prospective focus on a global pandemic.

### Looking Ahead

As with Congress, the Administration’s year will be broken up into a few segments:

#### Finishing the job (First half of 2024)

On the topic of finishing the job – the Biden Administration proposed several notable policy changes in 2023. Many are still in the proposed rule stage, meaning the Administration must still put together final regulations. Look for the Administration to finish the bulk of that work over the next six months, in part to avoid challenges through the Congressional Review Act (CRA). The CRA allows Congress to nullify a rule with fast-track Senate consideration through a vote by both chambers. The fast-track process is only available if the resolution is considered within 60 Senate session days of the rule’s issuance. The resolution of disapproval must be signed by the President so the CRA has only been successful when the opposite party takes over the Presidency.

However, we also anticipate the Administration will not be content to sit firm on the current list of accomplishments. For example, the White House released an Executive Order directing CMS to identify new payment models for drug policy just weeks before the midterm election – a marker meant to drive additional headlines before the election. To that end, don’t be surprised if we see the Administration remain active and creative on:

- Prescription drug policy – Yes, the Inflation Reduction Act is settled law. But the Biden Administration sees great opportunity in remaining active in this field, as demonstrated by a number of actions in 2023. Look for additional calls for Congressional action, new demonstrations by the CMS Innovation Center, new program policy, and new executive orders.
- Coverage rates – Dating back to the 2018 general elections, Democrats have seen great opportunity in campaigning on the coverage policies created by the Affordable Care Act. Look for Democrats to continue to advance national efforts to drive more coverage through the marketplace, with a focus on impact to consumer costs.

#### The great “hush” (Summer – election day)

The great “hush” is our term for an informal period between the summer before an election and the election itself when agency traffic typically shrinks to a minimum. That doesn’t mean it’s all quiet – the Administration may very well still put out carefully tailored announcements and messaging underscoring the track record on key policy areas – including announcing the results of the initial round of negotiations with drug manufacturers under the Inflation Reduction Act – as well as charting out future work in a second term.

#### Post-election scramble

If President Biden does win re-election – no big deal, the Administration gets four more years. Should President Biden not be re-elected in November, every political appointee in the executive branch starts to ask the question – how do we maximize our impact on the executive branch beyond inauguration day? The Trump Administration certainly did so, keeping the Federal Register busy in the closing days.

## *Upcoming Deadlines*

### **Expired Provisions 2023**

- Expired September 30:
  - The President's Emergency Plan for AIDS Relief (PEPFAR) Extension Act of 2018 partially expired
  - Pandemic and All-Hazards Preparedness Act (PAHPA)
  - Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act
  - Funding for Medicare quality measure endorsement, input, and selection
  - Funding Medicare outreach and assistance for low-income programs (\$50 million for each fiscal year)
  - Funding for the Medicaid Money Follows the Person Rebalancing Demonstration program at \$450 million per fiscal year
  - Protections against spousal impoverishment for partners of Medicaid beneficiaries who receive home and community-based services
  - Community mental health services demonstration program
- Expired December 31
  - The Independence at Home medical practice demonstration program

### **Expiring Provisions 2024**

#### **Appropriations:**

- March 1: The Agriculture-FDA, Energy-Water, Military Construction-VA, and Transportation-HUD bills expire
- March 8: The Commerce-Justice-Science, Defense, Financial Services-General Government, Homeland Security, Interior-Environment, Labor-HHS-Education, Legislative Branch, and State-Foreign Operations bills expire

#### **Authorizations:**

- Expiring January 19
  - Community Health Centers

- National Health Services Corp
- Teaching Health Centers that Operate GME
- Special Diabetes Program and Special Diabetes for Indians Program
- Disproportionate share hospital (DSH) reductions resume
- Personal Responsibility Education Program (PREP)
- Sexual Risk Avoidance Education (SRAE) program
- Medicare work geographic index floor

### **Longer-Term Expiring Provisions**<sup>[2]</sup>

- Debt Ceiling: Suspension of the debt limit expires January 1, 2025.
- End of 2024: Statutory PAYGO cuts from the American Rescue Plan Act (ARPA) will take effect
- End of 2024: Current Medicare physician Alternative Payment Model (APM) thresholds expire (based on performance year 2022).
- End of 2024: Medicare COVID telehealth flexibilities expire
- End of 2024: Delay of certain laboratory reporting requirements used to determine payment rates for clinical diagnostic laboratory tests under Medicare
- FY 2027: September 30: Food and Drug Administration User Fee Programs expire:
  - Prescription Drug User Fee Act (PDUFA VII)
  - Biosimilar User Fee Amendments (BsUFA III)
  - Generic Drug User Fee Amendments (GDUFA III)
  - Medical Device User Fee Amendments (MDUFA V)
- FY 2028
  - Medicare Hospital Insurance (Part A) Trust Fund exhaustion
  - Food and Drug Administration user fees for animal drugs (ADUFA) and animal generic drugs (AGDUFA)<sup>[3]</sup>
- FY 2029: September 30: Children's Health Insurance Program

<sup>[2]</sup> <https://www.crfb.org/blogs/upcoming-congressional-fiscal-policy-deadlines>

<sup>[3]</sup> Reauthorization approved as part of HR 5860, the Continuing Appropriations Act, 2024 (PL 118-15)

## *Medicare*

Medicare remains a popular government program, impacting medical care for millions of seniors. Those dynamics make Medicare fertile ground for politicization, but also ripe for bipartisan dialogue.

### **The Administration**

Make no mistake – the Biden Administration would like the voters to see Medicare as an issue of strength for the President headed into 2024.

The Biden Administration has made clear that “protecting Medicare” will be a high-level theme through 2023 and 2024. To that end, President Biden and other messengers have highlighted proposals from different Republican policymakers that would make changes to the Medicare program – though none of those policy reforms appear to be a part of the official platform, or the current strategy for leadership.

Expect ongoing messaging from the Administration about “protecting Medicare” and other changes to the program impacting seniors.

The key themes we are watching from the Administration:

- Health Equity Social Determinants of Health
- Drug Pricing Policy

### *Medicare fee-for-service*

- **Drugs!** – As the Administration looks under every rock for messaging points on prescription drugs, changes in one area have been glaringly missing for the moment: Part B drugs. While the Inflation Reduction Act made some tweaks, it largely left the base payment rate for drugs administered through Part B untouched.
  - **Demos** – The Biden Administration has not yet followed the lead of the Obama and Trump Administrations to (attempt to) use the authority of the Center for Medicare and Medicaid Innovation to modify the standard formulary of Average Sales Price plus 6%. The Administration has announced plans to pursue a demonstration that would change reimbursement rate for products approved under the FDA’s accelerated approval pathway; however, the Administration has also indicated that demo is on the shelf for the moment.

- **Fiddling with the rules** – Medicare pays for drugs that get to patients in a number of different settings: inpatient procedures, infusion centers, the doctor’s office, etc. CMS updates the rules for each of these payment systems every year – and can offer some surprises in the process. They aren’t always messaging tools – sometimes CMS just makes policy changes for unexpected reasons.
  - For example, last year, CMS updated the application dates for the New Technology Add-on Payment (NTAP) in the inpatient setting, requiring a drug have Food and Drug Administration (FDA) approval earlier in the year to qualify – potentially narrowing the scope of drugs eligible for the payment.
- **Prices for the first negotiated drugs** – Keep an eye out in September for when CMS releases the negotiated prices for its first tranche of 10 drugs.
- **Sufficiency of payment updates** – CMS conducted another standard year of updating Medicare fee schedules, punching in the standard geographic and cost factors. However, providers are increasingly unimpressed with what CMS is offering, particularly during a period where costs have risen significantly, and (arguably) aren’t reflected in the updates CMS offers. Look for providers to continue to push CMS to use more recent cost data in estimating impacts.
- **Medicare coverage policy and TCET** – In 2021, CMS paused and rescinded a Trump-era rule that would have offered guaranteed Medicare coverage to medical devices approved under the Food and Drug Administration's (FDA) breakthrough pathway. In its place, earlier this year, CMS proposed a new approach – the Transitional Coverage for Emerging Technologies (TCET) pathway. Look for CMS to finish tinkering with the pathway and finalize it in 2024.
- **Value-Based Care** – The Administration has set a lofty goal of having 100% of Medicare beneficiaries in accountable care arrangements by 2030 (not necessarily accountable care organizations (ACOs)). This year, we saw the Administration launch two new models focused on primary care providers – Making Care Primary and the AHEAD Model – providing clinicians with additional options for value-based arrangements.
  - **New mandatory Alternative Payment Models (APMs)** – CMS has forecast plans to develop two APMs through the regulatory process, signaling that participation for some providers may be mandatory. One is designed to impact the organ transplant process, while the other will be an episodic model.
  - **Beyond ACO REACH?** – A looming issue beyond the horizon: what will become of the ACO REACH model and its participants when the current model wraps up in 2026?



- **Social Determinants of Health (SDOH)** – Virtually every Medicare fee-for-service rule that the Biden Administration has released has been accompanied by an explanation of how the rule supports health equity. We expect this trend to continue. Last year, Medicare adopted several new billing codes intended to reimburse providers for additional time spent assessing patient needs for SDOH. Look for those types of interventions to continue.
- **Nursing Home Regulation** – Coming out of the COVID-19 pandemic, the Biden Administration signaled a strong interest in stricter regulation of the nursing home industry, using the levers provided from Medicare and Medicaid. The big move in 2023 – new proposed requirements for nursing homes to maintain certain staffing levels as a condition of participation in Medicare and Medicaid. More recently, the Administration has signaled an intention to push off finalizing that rule until 2026. However, it's possible the Administration will find other paths to tightening the rules for nursing homes.

*Medicare Advantage and Part D*

- **Inflation Reduction Act changes continue** – The Inflation Reduction Act made some significant changes to Medicare Part D. While the lion's share of those changes take effect in 2025, some important changes hit in 2024 – namely a new beneficiary cap on out-of-pocket costs. Look for significant guidance from CMS on how to plan for the bigger changes hitting in 2025.
- **Part D premium disruptions** – Academics and researchers are starting to notice some big changes in Part D premiums, which could become worrisome for the Biden Administration. Part D premiums in stand-alone plans jumped from \$40 to \$48 in 2024; next year we may see the same, as Part D plans wrestle with how to price the impact of the IRA changes. Can the Biden Administration do anything to stop the increases?



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The Biden Administration made major strides in implementing the Inflation Reduction Act in 2023, but the work is far from complete. In addition to troves of additional guidance on Part D redesign and smoothing yet to come, we'll get a reasonable indication of exactly how 'fairly' Medicare intends to conduct price negotiations and whether the negotiation program can withstand substantial legal challenges before the year is out. Look for Democrats to attempt to hammer home the positive impacts of their signature legislative achievement over the past four years ahead of an impactful election, many of which may not materialize before then.





- **Payment changes, some big, some small** – For Medicare Advantage payment, 2023 was one of the more impactful years in recent memory. CMS finalized an overhaul of the risk adjustment methodology (to be phased in over three years) and finalized new rules of the road for the long-stalled audit function, the Risk Adjustment Data Validation (RADV) program.
  - **Fewer waves on Medicare Advantage** – After a disruptive 2023, look for CMS to offer calmer waters on Medicare Advantage payment in 2024. We expect CMS will continue with the scheduled phase-in of the risk adjustment model finalized last year.
  - **Big year for Part D** – As noted earlier, the Inflation Reduction Act made major changes to the structure of the Part D benefit, shifting the responsibility for costs away from beneficiaries and the government on to plans and manufacturers. Those changes impact the relative cost to plans of different beneficiaries – and thus necessitate an overhaul of the Part D risk adjustment model, which is in the works for 2025. We anticipate this reform could have a significant financial impact on plans.
- **Dually eligible beneficiaries** – The Biden Administration has shown an interest in ensuring dually eligible beneficiaries are in products that integrate their Medicare and Medicaid benefits – including Duale Eligible Special Needs Plans (D-SNPs). Look for the Biden Administration to continue fine tuning Medicare Advantage policies with an eye toward this audience.
- **Medicare Advantage skepticism and regulation** – While CMS may not be blowing up Medicare Advantage payments in the same way next year, the agency does continue to pursue some notable reforms to the program.
  - **Supplemental benefits** – While the Biden Administration has acknowledged the potential impact of supplemental benefits in addressing the social care needs of some beneficiaries, it also has shown a healthy dose of interest in better understanding the benefits. Look for CMS to continue efforts to promote transparency on utilization of supplemental benefits.
  - **Marketing** – In 2023, CMS implemented significant new restrictions on Medicare Advantage marketing practices, including new constraints on advertisements and rules for in-person sales meetings. CMS has proposed even more changes for 2025, placing new constraints on agent/broker compensation. Look for the Administration to continue ramping up enforcement and regulation of how plans are sold to beneficiaries.
  - **Prior Authorization** – CMS made significant changes to rules for prior authorization (medical benefits only, not drugs) effective 2023. Another sweeping regulation, in the final stages

- of review, would require greater automation and faster turnarounds of prior authorization requests. Expect continued scrutiny of this practice and its impacts.
- **Innovation Center activity?** – Through the CMMI, CMS has some authority to tinker with Medicare Advantage and Part D – which can be a helpful tool for messaging and other exercise.
  - **\$2 Drug Demo** – In early 2023, the Biden Administration announced plans to pursue a \$2 drug demonstration for Medicare Part D, in which participating plans would agree to cover a CMS-determined list of generic drugs for no more than \$2/month. To date, we haven’t seen CMS move ahead on that demonstration – but don’t be surprised to see an effort to do so in 2024.
  - **Other moves?** – Given this Administration’s laser focus on drug costs, could we see the Administration look to use CMMI authority to make other moves – perhaps to address looming Part D premium increases?

*Regulations and Dates to Know*

- **Medicare Advantage Rate Announcement** – Each year, CMS is required to make changes to the methodology used to calculate payments to Medicare Advantage and Part D plans in an annual Rate Announcement.
  - Final Rate Announcement – First Monday in April (by statute)
  - Advance Notice (draft Rate Announcement for comment) – At least 60 days prior to publication of the Rate Announcement
  - Big, big caveat – If Democrats lose the November 2024 presidential election, look for the Administration to consider rushing the 2026 Rate Announcement to have it done by inauguration day.
- **Medicare Advantage and Part D rules** – CMS has already issued a few proposed rules that are likely to be finalized next year:
  - 2025 Regulation – CMS issued a proposed regulation making a bevy of changes impacting supplemental benefits, dually-eligible beneficiaries, and agent/broker compensation. Look for that rule to be finalized in the first quarter of 2024.
  - Prior Authorization – CMS issued a proposed regulation creating new parameters for the use of prior authorization in Medicare Advantage (not applicable to drugs). The rule appears to be in the final stages of review, though it would not take impact until 2026.
- **Medicare fee-for-service regulations** – Regulations updating the rules and amounts of Medicare payments under fee-for-service are updated through an annual rulemaking cycle. These rules travel on two schedules:

- Fiscal Year
  - Proposed rule – Spring (April)
  - Final rule – end of July (statutory requirement)
  - Hospital inpatient payment, skilled nursing facilities (nursing homes)
- Calendar Year
  - Proposed rule – late June/early July
  - Final rule – end of October (statutory requirement)
  - Hospital outpatient, physician fee schedule, home health, hospice, ESRD/dialysis.
- **Prior authorization** – In 2022, CMS proposed significant changes to prior authorization rules, applicable to Medicare Advantage, Medicaid managed care, and the commercial market. Changes include requiring electronic prior authorization platforms, and stricter time frames for decisions. Look for this final rule early next year. When the Administration finalizes the rule there will be renewed Congressional action legislation in this area.

## **Congress**

### *Oversight*

- Medicare Advantage – In 2023, oversight of Medicare Advantage was a frequent topic of scrutiny. Inquiries from Capitol Hill targeted marketing (Senate Finance Committee), prior authorization (multiple), the use of artificial intelligence, and payments. Of note – requests are coming from both sides of the aisle at this point.

### *Bipartisan Activity*

Yes – many of these issues were on our list from last year. But the unexpected focus on PBM reform deferred further activity on a number of issues likely due for some additional focus.

- **PBM Reform** – Few industry watchers predicted the sudden fascination with PBMs that hit Capitol Hill this year, with members of both parties and both chambers pouring countless hours into the development of multiple bills impacting Medicare, Medicaid, and the private sector. The work is not yet done; look for Congress to advance some quantity of these policy changes in early 2024 as part of a larger package.
- **Physician Payment Reform** – Passage of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) was intended to end the era of payment cliffs, including incentives for clinicians to transition to alternative payment models like accountable care organizations. Instead, 2023 marks the fourth consecutive year of Congress being asked to subvert a scheduled cut. Further urging the conversation – a new report from the Congressional Budget Office finding that CMMI actually was a net cost to the

- government rather than a saver. The time is ripe for Congress to take a bipartisan review of physician payments – though any concrete action would likely be deferred to the lame duck session and beyond.
- **Dually Eligible Beneficiaries** – Policymakers from both parties can trace many of the highest cost patients in Medicare and Medicaid to those enrolled in both Medicare and Medicaid. To that end, we have seen bipartisan proposals floated in the last Congress to modify how government programs interact with those beneficiaries, with an interest in moving them to products that fully integrate their Medicare and Medicaid benefits through a single channel. A bipartisan group of Senators followed a 2022 Request for Information by releasing draft legislation that would invoke the use of passive enrollment, among other changes. Look for that work to continue, with the caveat it’s a long way from passage at the moment.
- **Telehealth** – The COVID-19 pandemic supercharged the nation’s interest in telehealth, and the federal government sought to develop policies that kept pace with the new interest. Notably, Medicare suspended a number of its historical constraints on paying for services offered by telehealth, using emergency authorities. With the end of the Public Health Emergency, Congress has swooped in to extend many of those flexibilities – but only for limited terms. The most recent extension expires at the end of 2024, setting up Congressional action in the lame duck session.

## Medicaid

The politics of Medicaid are strikingly different from Medicare, with both parties viewing the role of the program differently. These competing visions lead to significantly different philosophies, and, for the executive branch, policy outcomes.

### The Administration

- **“Unwinding” from the Public Health Emergency** – In spring 2020, Congress provided states with a higher federal matching rate, anticipating the impact of the COVID-19 pandemic on the economy. As a condition of accepting the higher matching rate (which all states did), Congress prohibited Medicaid programs from dropping anyone from coverage for any reason through the duration of the Public Health Emergency. At Congress’ direction, that policy finally came to a close in March 2023 – almost three years after Congress first enacted it. With the end of continuous enrollment, states had 14 months to review and re-establish the eligibility of all Medicaid enrollees.

The process has been....bumpy. Disenrollments topped 10 million, with the majority being “procedural” disenrollments in which states were unable to undertake a redetermination based on a lack of information from the beneficiary. CMS has taken some steps to push the states, including public letters highlighting access issues like call center wait times. More recently, CMS also moved into regulation enforcement steps the agency can take for states found to be out of compliance with federal rules for the redetermination process.

If CMS intends to drop the hammer on any state, the window to do so is closing. The formal redetermination period should come to a close in the first six months of 2024. An extension of the initial 14 months may be inevitable for some states, though many will be glad to have the process behind them.

- **Drugs!** – Again, leaving no rock unturned, we anticipate the Biden Administration to look for policy movement in the drug pricing arena.
  - **Changes to Medicaid Drug Rebate Program** – In May 2023, CMS unexpectedly proposed some significant changes to the Medicaid drug rebate program. Changes included “stacking,” which would modify how drug manufacturers calculate the “best price” on which many rebates are based; a new “drug

- price verification survey,” in which CMS can collect significant new information from manufacturers; and an expansion of what drugs and therapies are subject to rebates. According to official schedules, CMS anticipates finalizing the rule in June – toward the later end of when the Administration can finish regulations without fear of Congressional reversal.
- **Gene and cell therapies** – The FDA has begun to approve (exciting!) new gene and cell therapies that offer the opportunity to make impactful, “durable” changes for beneficiaries living with a number of chronic conditions. Recent headlines have accentuated multiple products coming to market to treat – and potentially cure – sickle cell disease. However, these new products come with access and budgetary concerns for states. CMS has (seemingly) embraced a policy of outcomes-based arrangements, changing rules for Medicaid drug price calculations under the Trump Administration, and now launching a new CMMI demo under which CMS will negotiate these agreements on behalf of states who opt in. The Biden Administration moved up the start date for the demonstration from 2026 to 2025, seemingly realizing the therapies are hitting the market already. We expect CMS to release details for this model in January.



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The biotech industry has highlighted the access challenges to gene therapies for patients with Medicaid. Now, with two gene therapies for Sickle Cell Disease approved in December, the spotlight is on whether the payers were ready, if there are access delays compared to the commercially insured, and the impact on program budgets.



- **Home and Community-Based Services** – Going back to 2021, the Biden Administration has shown an interest in finding ways to drive more federal dollars to home and community-based services, with a particular focus on bolstering salaries for direct care workers and others. Look for CMS to finalize the “Medicaid Access Rule” in the spring, which would require 80% of Medicaid funds going toward these direct care services to go to worker salaries and put new transparency mandates on states with respect to provider rates.
- **Medicaid managed care** – It’s seemingly a rite of passage for every Administration to take a shot at rewriting the regulations governing Medicaid managed care, and this one followed the trend with a CMS proposed rule earlier this year. The update

- included a myriad list of policies, including changes to the Medical Loss Ratio policy.
- **Creative waivers** – The differing perspectives of the two parties typically show up in how CMS considers requests from states for waivers and other demonstrations. The Biden Administration has rejected state waiver requests for work requirements, while approving a number of requests to use Medicaid dollars on social determinants of health. Look for CMS to continue creative approaches to waiver approvals in 2024.
- **Supplemental payments, including managed care** – In 2023, CMS showed some signs in digging into oversight of supplemental payments and other program issues – though, certainly not to the level of the previous Administration.
  - Constraints on “state-directed payments” – In the proposed managed care rule mentioned earlier, CMS proposed new caps on the total compensation providers can receive through state-directed payments – specifically capping at the average commercial rate. However, CMS also toyed with more restrictive policies in the rule, such as capping these payments at Medicare fee-for-service rates or placing state-wide caps on total state-directed payments. We’ll find out how far CMS is willing to go in a final rule this spring.
  - Additional bulletins to states – Earlier this year, CMS issued a notice to all states warning of “pooling” arrangements and “hold harmless” prohibitions for provider taxes. While that directive is now being reviewed by the courts, CMS could opt to look toward subregulatory approaches like state memos to lead program integrity efforts in lieu of making more aggressive changes to state financing policies.

#### *Regulations and Dates to Know*

- **Medicaid drug rebate rule** – Last May, CMS proposed a number of changes to the Medicaid Drug Rebate Program, many of which have generated significant controversy in the manufacturer community. According to the most recent agenda from the Administration, the target for a final rule is June.
- **Medicaid “access” rule** – CMS proposed a rule making several changes to the oversight of provider payment rates, including a new requirement for 80% of Medicaid funds for some types of home and community based services to go toward provider salaries. Look for CMS to finalize this regulation in the spring.
- **Medicaid managed care rule** – As noted earlier, CMS proposed changes to Medicaid managed care policy. Again, look for CMS to put a bow on that rule in the spring.
- **Prior authorization** – In 2022, CMS proposed significant changes to prior authorization rules, applicable to Medicare Advantage,



- Medicaid managed care, and the commercial market. Changes include requiring electronic prior authorization platforms, and stricter time frames for decisions. Look for this final rule early next year.

## **Congress**

### *Oversight*

- **The end of the COVID-19 Public Health Emergency and the beginning of Medicaid redeterminations** – Same issue described before, only with higher stakes as the redetermination period comes to a close. House Republicans may look to make sure that the Biden Administration doesn't wrongfully tie the hands of states looking to complete the redetermination process on an aggressive timetable. Democrats from both parties are likely to push CMS to do what it can to stem coverage losses.
- **Program Integrity** – In 2023, Republicans sent multiple letters to CMS calling for better oversight of Medicaid payments, typically following up on government watchdog reports noting improper payments, including payments for deceased beneficiaries. Expect Republicans to continue this oversight.

### *Bipartisan Work*

- **Gene and cell therapies** – Advances in science and medicine continue to reshape the landscape of medical care. In recent years, pharmaceutical manufacturers have begun the process of bringing gene and cell therapies to market, which hold curative and life-changing potential for advanced blood cancers (CAR T-cell therapy), sickle cell, and other diseases.

Given the nature of their one-time use, the therapies carry a price tag that presents challenges for the Medicaid program. The rigid nature of state budget cycles makes these new therapies a challenge for Medicaid programs. Look for Congress to consider what federal levers can be applied to ensure Medicaid beneficiaries get access to these therapies when they come to market. To that end, Senate HELP Committee Ranking Member Bill Cassidy (R-LA) has released a Request for Information on these therapies, and Representatives Guthrie and Eshoo advanced the MVP Act through Committee last session which would grease the skids for outcomes based arrangements.



## *Commercial Insurance – Employer Market and the Marketplace*

Make no mistake – the marketplaces created by the Affordable Care Act remain a cornerstone of the Biden Administration’s health care priorities, and an area where Democrats are jumping at the opportunity to make contrast with House Republicans. In 2024, look for Democrats to take every opportunity to talk about the marketplace – and for Republicans to try and muddy the water.

### **The Administration**

- **All-in for the marketplace** – The Biden Administration’s focus on the marketplace extends beyond formal policy. The Administration will extend every effort to promote the marketplace and opportunities for enrollment – and then trumpet the results.
- **The mess that is Surprise Medical Billing implementation** – In December 2020, Congress passed bipartisan legislation – the No Surprises Act – that put new constraints around “Surprise Medical Billing,” specifically limiting patient copays to the typical cost of in-network care in those instances. The legislation also created a mechanism to settle disputes between health plans and out-of-network providers who treat their enrollees in these instances. However, implementation of these provisions has been...bumpy. The Administration has been surprised by the high number of filings with the new independent dispute resolution process, and providers have successfully challenged a number of the rules CMS has put out, with the courts repeatedly finding CMS went outside the original intent of the statute. CMS has more work to do to finish straightening out this process next year – look for more rules, and possibly more court cases depending on what the rules say.



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Congress is increasingly concerned the Biden Administration’s implementation of the law is distorting incentives around negotiations in the commercial marketplace between health plans and providers and destabilizing networks. I anticipate more friction between Congress and the Administration and strident advocacy by key stakeholders in 2024.



- **Short Term Limited Duration Plans** – In that same vein of promoting coverage through the marketplace, the Biden Administration has shown an interest in tamping down on plans that aren't subject to the Affordable Care Act's coverage mandates. Over the summer, the Biden Administration proposed a rule that would change rules for short-term health plans, as well as impact fixed indemnity plans and others. We expect the Administration will finalize that rule in the first half of next year.
- **Prior authorization** – Turns out providers are mad about prior authorization from all kinds of health plans, not just Medicare Advantage and Medicaid managed care. CMS is in the process of finalizing a new rule on prior authorization across all the programs that would put constraints on how plans implement the process.
- **Pressure campaign on Congress** – Part of the Biden Administration's efforts in 2024 will no doubt call for Congressional action in the commercial marketplace.
  - **Capping the cost of insulin** – In the Inflation Reduction Act, Congress capped the monthly out-of-pocket costs for Part D beneficiaries for insulin. However, efforts to create a similar cap in the commercial market fell to the wayside due to process issues. The Biden campaign clearly intends to keep harping on the issue in 2024.
  - **Subsidies for the marketplace** – In the American Rescue Plan Act – a partisan COVID relief bill passed under President Biden in early 2021 – Congress significantly bolstered the subsidies for purchasing insurance on the federal marketplace through 2025. The Biden Administration will spend a fair amount of time and energy in 2024 pushing Congress to re-up the tax credits in the future as a part of the messaging campaign on the Affordable Care Act. Given this is one of a number of tax policies that expire in 2025, consideration of extending the enhanced premium tax credits will likely be considered by the next Congress.
- **State waivers (1332)** – The Affordable Care Act allowed for the use of state innovation waivers (Section 1332 waivers) that allow states to waive aspects of the law's requirements if other metrics are met. The Trump Administration saw great opportunity in these waivers and approved some controversial changes. To date, we haven't seen the Biden Administration put significant effort into the use of waivers. However, election years can do funny things.
- **In event of an Administration change...** – If Democrats lose in November, we expect the Biden Administration would rush to leave their impact on the marketplace for 2025 and beyond. The Administration could move up the annual Notice of Benefit and Payment Parameters and take other steps to try and lock in the current approach of the Administration for as long as possible.

*Regulations and Dates to Know*

- **Notice of Benefit and Payment Parameters** – Each year, CMS updates the rules for the individual and group markets that fall under the agency’s purview, along with the marketplace. This update occurs through the Notice of Benefit and Payment Parameters (NBPP). CMS has issued a proposed NBPP for 2025. Look for CMS to finalize that regulation early next year. However, as noted earlier, if President Biden is not re-elected in November, look for the Administration to consider rushing through the 2026 NBPP later this year.
- **Prior authorization** – The same regulation noted in the Medicare and Medicaid sections also apply to plans sold on the marketplace. CMS issued a proposed regulation creating new parameters for the use of prior authorization in these plans (not applicable to drugs). CMS is likely to finalize the rule next year, though it would not take impact until 2026.
- **Mental health parity** – Earlier this year, the Administration proposed a rule updating requirements for parity in coverage for physical and mental health services. Look for the Administration to try and finish that rule in the first half of next year.

**Congress***Oversight*

- **Surprise Medical Billing** – The Hill has offered bipartisan criticism of how CMS has implemented the No Surprises Act regulations. Look for continued interest in this topic in 2024.
- **Questions of the ACA/cost of health care** – Nobody was happier than Democrats when former President Trump suggested he’s look at alternatives to the Affordable Care Act should be return to office, and Congressional Republicans seemed largely uninterested in raising the topic. However, if the Biden Administration plans to make coverage through the marketplace a campaign issue, it stands to reason Congressional Republicans will try and muddy the message, with questions on the cost effectiveness of the federal subsidies and other challenges.

*Bipartisan Work*

- **PBM Reform** – As noted earlier, Congress has been exploring bipartisan reforms to the PBM industry throughout 2023 – including changes to the commercial market. Many of these changes are candidates for inclusion in a health package in early 2024; if not, Congress could continue work on those policies, and potentially revisit down the road.

- **Insulin caps?** – The Biden Administration has been vocal about extending out -of-pocket caps for insulin to the commercial marketplace, which requires action from Congress. We've seen bipartisan interest in the topic in the Senate, and work could continue there. However, it's not clear the House is quite as eager to move on the topic.

## Food and Drug Administration

The human medical product user fee programs were reauthorized as part of the late December 2022 omnibus legislation, along with a number of FDA-related policy riders (collectively dubbed the Food and Drug Omnibus Reform Act (FDORA)). Because of that, 2023 was a relatively slow year in FDA world, at least with respect to the volume of bills moving through committees to the floor.

### The Administration

- **FDORA deadlines** – The 2022 omnibus legislation that carried multiple FDA provisions included requirements for the agency to issue guidance documents by the end of 2023 on several specific topics such as implementation of the new advanced manufacturing technology designation program (recently released) and clinical trial diversity plans (still outstanding).
- **Diagnostic tests** – In September 2023, FDA issued a proposed rule that would phase in the agency’s active regulation of LDTs as medical devices. Despite widespread requests for extension, the comment period closed in December and the agency seems to be intent on finalizing the regulation in the spring of 2024, at least in part with the potential CRA play in mind. Once the rule is finalized, it is widely expected that litigation will ensue.
- **Product shortages** – Look for the Administration to continue to lean on the FDA, along with the Administration for Strategic Preparedness and Response (ASPR), to use its current authorities to help prevent and alleviate shortages of medical products, including sterile injectables. In tandem, look for FDA to continue to prod Congress to provide the agency with expanded authorities and additional reporting requirements on manufacturers.



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The universe of policy ideas to address drug shortages in the FDA space is only growing. Some targeted provisions could get pulled into an agreement on PAHPA that, if reached, will likely need to wait on a future funding vehicle.

Considering that exercise in relation to FDA’s medical countermeasure PRV program awaiting reauthorization since last September and the rare pediatric PRV program expiring this September, we have a busy year ahead of us on the FDA desk.”



## Congress

### *Oversight*

- In addition to FDA Commissioner Califf testifying on the FY2025 budget, there could certainly be hearings with FDA leadership on issues ranging from FDORA oversight to tobacco and food center reforms to the diagnostic testing debate.

### *Bipartisan Work*

- **Diagnostic tests** – While FDA has proposed to more actively apply its current medical device requirements to LDTs via regulation, Congress has spent a significant amount of time over the past several years, both publicly and behind the scenes, discussing what legislation modernizing how diagnostics are regulated could look like. The VALID Act in the House, which would establish a new regulatory framework at FDA for both lab and manufacturer developed diagnostics, has been the focus of most of the debate and will likely be discussed at a hearing in relation to FDA’s proposed approach. Whether there is a bipartisan path forward from there next year is a bit murkier.
- **CBD** – After multiple years thinking through whether the agency was comfortable using its current authorities to regulate hemp-derived cannabidiol (CBD), FDA communicated that a new approach was necessary that would require legislation. A bipartisan, bicameral request for information was released earlier this year and there could be a renewed push for federal clarity in the new year.
- **Shortages** – There are different perspectives on the Hill about what if any legislation would be helpful to address drug shortages, particularly when it comes to the FDA. While Democrats have been more supportive of placing additional reporting requirements on manufacturers that FDA would enforce, Republicans have primarily focused on potential changes to reimbursement policy. They will need to find common ground for anything to move in this space.
- **Priority Review Vouchers (PRVs)** – There are several PRV programs at FDA intended to incentivize the development of drugs for particular populations and disease areas. The medical countermeasure (MCM) PRV program expired September 2023 and has yet to be reauthorized, while the rare pediatric disease PRV program is set to expire September 30, 2024. There are different perspectives on whether PRVs are an appropriate incentivizing mechanism and, unless the MCM PRV program is reauthorized in an upcoming funding package, debate around both programs could merge into a combined exercise. Additional pediatric policies impacting FDA and drug developers could also arise.

## Public Health

### The Administration

- **ARPA-H** - Molded after the military’s Defense Advanced Research Projects Agency (DARPA), the biomedical version, the Advanced Research Projects Agency for Health (ARPA-H), aims to support high-risk, cutting-edge “transformative” research. The agency is now up and running, with leadership and staff in place, and plans for the different ARPA-H offices in place. Look for ARPA-H to begin making investments in research projects.
- **The “Cancer Moonshot”** - Then President Obama tapped President Biden to lead a “Cancer Moonshot” effort intended to bolster research and support for cancer treatments. President Biden has opted to reinvigorate that effort - though, it’s hard to anticipate where that course will go next year and critics have pointed out the IRA will have a negative impact on the development of new cancer therapies and new cancer indications for existing drugs.



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2024 promises to be a busy year for public health. Not only must the Congress pass continued funding for Community Health Centers, they also must tackle their overdue reauthorization of PAHPA. This will present both threats to, and opportunities for, affected stakeholders. Continued engagement with policymakers will remain essential.



### Congress

#### *Oversight*

- **Federal response to COVID-19** - The COVID-19 pandemic may be over, but it’s not clear whether Congressional oversight on the matter is over. No question, House Republicans formed a committee, held hearings, and fired off letters at a busy clip. However, House Republicans may have more questions yet to ask.

#### *Bipartisan Work*

- **Pandemic and All-Hazards Preparedness Act (PAHPA)** - In December 2006, Congress passed the [original](#) Pandemic and All-

- Hazards Preparedness Act (PAHPA), which established the Administration for Strategic Preparedness and Response (ASPR) and the Biomedical Advanced Research and Development Authority (BARDA). ASPR manages the nation's Strategic National Stockpile (SNS) and leads the [Public Health Emergency Medical Countermeasures Enterprise](#) (PHEMCE) which coordinates the priorities and deployment of countermeasures. BARDA supports the development of medical countermeasures. Over time, the bill and programs under these entities have grown in scope and size through its reauthorizations in 2013 and 2019.

Some PAHPA authorities expired earlier this fall. In anticipation of that expiration, committees in both chambers held hearings and developed legislation. However, PAHPA reauthorization has become more political than in previous cycles and ancillary policy priorities have complicated its path forward. While there is an outside chance that reauthorization – or components from the legislation reported out of the committees – could be included in the January funding package, PAHPA may very well remain unauthorized for the better part of 2024.

- **Community Health Centers** – Mandatory federal funding for Community Health Centers comes up for renewal periodically in Congress. That funding ran out at the beginning of the fall but was patched through to January 19. We expect that Congress will officially renew the funding in early 2024.
- **CDC Reform** – We've seen some interest from Republican thought leaders on making some changes to the CDC's statutory authority. It's not yet clear that these efforts would be bipartisan – but there's probably a path for some joint work coming out of the COVID-19 pandemic.



## *Artificial Intelligence*

Ever since ChatGPT hit the market, it seems as though nobody can stop talking about artificial intelligence (AI). No doubt, AI is already playing important roles in the health care sector. Now, the executive branch and Congress are racing to catch up and determine where regulation might be needed – but also where the opportunity could be from successful deployment.

Given the nascent stage of many of these topics, we're going to handle this section a bit differently. Rather than identifying specific activity between the Administration and Congress, we're offering a list of topics that have started to come to the surface in AI and could be discussed further in the coming year in either branch of the government.

### *Concerns*

- Algorithms and discrimination – The Biden Administration was seemingly ahead of the game on this one, as the August 2022 proposed update to anti-discrimination laws included a new provision explicitly extending discrimination requirements to internal algorithms provider use. The Administration has signaled this topic will continue to be an area of focus.
- Review of Claims and Prior Authorization requests – A few prominent investigative pieces popped up last year about health plans using AI programs to review claims and prior authorization requests. Those pieces made their mark, as they led to Congressional activity (oversight of plans and letters to CMS) and subsequent lawsuits. The Administration has also indicated it is doing its own research into how plans are using AI.
- Biological materials – A fall Executive Order from the Biden Administration called out the need to establish standards for “biological synthesis screening” to “protect against the risks of using AI to engineer dangerous biological products.”
- Consumer privacy – Early Congressional hearings repeatedly came back to the topic of privacy, as the massive flows of data needed to support broad deployment of AI raised questions of who will have what information.
- General questions about regulation – In those same early Congressional hearings, lawmakers repeatedly asked witnesses whether the federal government was asking all the right questions about regulation of AI. The FDA already has authority to review some products used in health care settings. But look for Congress and the Administration to continue thinking about what regulatory frameworks should be in place.

*Opportunities*

The federal perspective on AI is not all doom and gloom. Policymakers see significant opportunity from the deliberate and careful deployment of the technology. Some initial areas of interest:

- **Easing administrative burden** – Particularly for clinicians, concerns about the impact of paperwork and other administrative tasks on burnout have become quite loud. Policymakers do see enormous potential for AI, when implemented correctly, to lift the load on clinicians and at other steps in the process, freeing up more clinician time and potentially taking some administrative overhead out of the health care system.
- **Diagnostics** – A number of AI programs have been developed that can conduct their own reviews of patient records, including diagnostic imaging. In September 2022, the Government Accountability Office (GAO) issued a report asking why this technology was not more broadly deployed. Look for policymakers to dig into those questions as well.

## Other

While reimbursement policy often steals the show, meaningful oversight of the health care industry can come from different corners of the government. Some of the topics we’re tracking:

- Interoperability
- Civil Rights
- Competition Policy

### Administration

- **Exploring the “next phase” of interoperability** – The Department of Health and Human Services (HHS) and CMS will continue to use their positions – and payment streams – to push providers, health plans, and other health care stakeholders to engage productively on the exchange of health care data. However, there are also issues on the horizon relating to connecting patients with care outside of the traditional physical care – better engaging mental health care providers and providers of social care. Look for HHS to continue to lead discussions on those topics looking ahead.



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One thing the Administration, Congressional Democrats, and Congressional Republicans find some measure of mutual interest is on consolidation within the health care sector – expect continued attention there from both ends of Pennsylvania Avenue.



- **Abortion/reproductive rights** – The Supreme Court’s Dobbs ruling spurred a sea of activity in the Biden Administration, with a significant focus on the role of federal laws relating to discrimination and access. The HHS Office of Civil Rights has been active – and will continue to be active – in trying to draw bright lines relating to patient access to abortions and reproductive care, including support of federal challenges to new state laws popping up around the country.
- **Discrimination policy (more broadly)** – The Biden Administration has taken a sharply different perspective on implementation of federal anti-discrimination laws from the Trump Administration. In August 2022, the Biden Administration proposed a significant revamp of the laws included in Section 1557

- of the Affordable Care Act, which it will look to finalize at the beginning of next year. HHS has also proposed updates to anti-discrimination laws relating to disability policy.
- **LGBTQ+ protections** – The Biden Administration has been active on tailoring federal protections to the LGBTQ+ populations, working specific interpretations into several proposed rule changes to date. Look for the Administration to jump into new debates on gender affirming care for children.
- **Renewed vigor in merger scrutiny** – In 2021, President Biden issued an Executive Order, outlining an all of government approach to promoting competition policy – with initial interest in the health care sector, among others. Since that time, the FTC and partner agencies have revamped merger review criteria, launched investigations into the PBM industry, and begun weighing in on mergers. Expect the FTC and other agencies to continue broadening its perspective on mergers and consolidation and look for opportunities to make an impact.
- **Non-competes agreements** – In the spirit of the later point, the FTC proposed new regulations that would ban the use of “non-compete” agreements in employment contracts, with only a few limited exceptions. The broader business community is not a fan and is pushing back. We expect the FTC to try and resolve the issue one way or another next year.
- **Further labor regulations** – This year will see the continuation of a number of regulatory and enforcement actions the Administration has proposed – or are actively rolling out – impacting the relationship between employers and employees. The Department of Labor is seeking to constrain who may be considered an independent contractor, and the National Labor Relations Board is working to redefine and expand who may be considered a joint employer of workers. Further, the Federal Trade Commission and Department of Justice continue to pursue anti-competitive and anti-trust enforcement actions against various entities within (and outside) the health care sector.

#### *Regulations and Dates to Know*

- **Updates to HHS Anti-Discrimination Policy (1557)** – As noted earlier, HHS proposed some significant changes to anti-discrimination policy in August 2022 – many of which are likely to be viewed differently by a Republican Administration. Look for HHS to finalize these changes.
- **FTC rule on non-competes agreements** – The FTC proposed to do away with non-compete agreements earlier this year. If the FTC is going to finalize the change it likely will do so in the next few months.

## **Congress**

### *Oversight*

- Culture wars – Under the backdrop of the “silly season” of the 2024 elections, we anticipate Republicans in Congress will engage in oversight of the Biden Administration on hot button issues like abortion and gender transition services for children.
- Competition policy gone too far? – FTC Chair Lina Khan does not have many fans on the Republican side of the aisle in Congress. Look for Republicans to scrutinize the work of the FTC, even if many Republicans agree in principle on some of the hard look at consolidation.

### *Bipartisan Activity*

- Oversight of the big players – It doesn't seem to matter if you are a health system, a health plan, or some other large company in between. Congress seems interested in understanding how you got so big, and how the federal government can keep an eye on you. Look for parties on both sides to ask questions about consolidation and explore policy strategies that take away the incentives for mergers.