

**SPOTLIGHT REPORT**

January 10, 2022

## Regulatory Agenda Release Marks Biden's Pivot

**What's Happening:** The Biden administration released its latest semi-annual [Unified Agenda of Regulatory and Deregulatory Actions](#) last week, outlining its regulatory priorities.

**Why It Matters:** After a successful two years devoted to his legislative agenda while enjoying unified Democratic control of Congress, President Biden will now make a natural pivot to focusing on his regulatory priorities in the face of a divided government. The outlook for bipartisan legislation is dim in most areas, which means that the regulations from the Biden administration over the next two years will be crucial to demonstrating that the president is still able to wield power while also ensuring implementation of the series of new laws that are a cornerstone of his political legacy. While the pace of rulemaking is never as quick as the White House or its supporters would like, Biden has gotten more accomplished in his first two years than his recent predecessors – and with more attention coming from the White House and regulators being fully settled into their positions, this effectiveness is only likely to increase. There will be a shift, especially from those who have had the most time in office, to emphasize finalizing proposed regulations to ensure that they can also oversee the implementation phase. Doing so sooner rather than later is important given the inevitable legal challenges that many of the Biden administration's most transformative rules will face, especially in the wake of the Supreme Court's decision in *West Virginia v. EPA* last year.

**What's Next:** Although the majority of Biden's regulators have been confirmed by the Senate, there are still a handful of unconfirmed nominees for key positions including Gigi Sohn to be a commissioner at the Federal Communications Commission and Danny Werfel to head the Internal Revenue Service. The reason for optimism for the president and Democrats about getting them confirmed is that not only did Democrats retain control of the Senate, but they increased their effective majority to 51, which will eliminate some of the procedural hurdles that were needed in a 50-50 Senate. The Senate is in recess until January 23rd, but with legislation on the backburner for the foreseeable future, Senate Majority Leader Chuck Schumer (D-NY) will now be able to prioritize confirming Biden's remaining nominees.

## Overview

While the [Fall 2022 Unified Agenda](#) (UA) has slightly fewer total actions than the prior UA, there was a [jump in the number](#) of active economically significant actions from 220 to 244. These are regulations that agencies estimate to have an effect of at least \$100 million. These 244 actions are significantly more than any other president had in their fourth UA since 2000. Former President Barack Obama was the closest with 140 in his Fall 2010 UA. Biden has also completed the most economically significant rulemakings in this timeframe at 53, just edging Obama who claimed 51. **This sheer volume of rules is indicative of the torrid pace of rulemaking that Biden’s progressive regulators have embraced and one that we expect will continue over the next two years as the president gets fully behind them.**

One caveat to reading the UA is that it resembles more of a “Nice-To-Do” list instead of a “Must-Do” list. **Agenda items and timelines included in the UA are in no way binding and in many cases agencies will take longer than the listed dates.** A better way to view the dates is to see them as the earliest possible date by which action could happen, but knowing that it could be several months still from actually seeing that action come to fruition.

Below are selected regulations that are worth following over the coming months as they work their way through the rulemaking process.

## Financial Regulation

After spending much of the Securities and Exchange Commission’s (SEC) efforts over the last two years proposing rules, 2023 will see the agency move into the next phase where it will finalize many proposals and then have to defend the more controversial ones in big court battles. For prudential bank regulators, the focus will remain largely on finalizing the Basel III capital rules in a combined rulemaking led by the Federal Reserve and including the Federal Deposit Insurance Corporation (FDIC) and the Office of the Comptroller of the Currency (OCC). Notably absent from the UA was any mention of a new rule or change in the existing rules regarding bank mergers.

- **Market Modernization:** In a [series](#) of [four new proposals](#) released at the end of last year, SEC Chair Gary Gensler finally released his plans to restructure the equities market.
  - **Outlook:** While the new regulations stop short of banning payment for order flow, they still bring significant change, including the creation of auctions for some retail orders and allowing stock exchanges to execute orders at sub-penny increments. With the publication of the rules in December, it is probable that the SEC will not take final action on these proposals until 2024 at the earliest. These proposals will almost certainly be challenged in court, which will delay the implementation and could prevent Gensler from overseeing their

finalization.

- [Climate Change Disclosure](#): Under this rule, most public companies would have to disclose their risks from climate change in a uniform fashion, including Scope 3 emissions.
  - **Outlook:** This is one of Gensler's top priorities and as evidenced by the initial delay in its release, he is aiming to take every precaution to create a legally-defensible rule. Final action is not expected before April, but this could be delayed further as the SEC works its way through comments and considers any final adjustments. It is almost certain that whatever the SEC releases will face legal challenges, which will further delay the rule's effective date.
- [Enhanced Disclosures by Certain Investment Advisers and Investment Companies about Environmental, Social, and Governance \(ESG\) Investment Practices](#): This rule aims to increase the transparency of firms that label themselves as using ESG factors when making their decisions.
  - **Outlook:** This rule is part of Gensler's efforts, in his opinion, to ensure that investors are able to make fully informed decisions. The SEC is expected to complete the rulemaking process no earlier than April, but this timing could slip. This rule too is expected to face legal challenges, which will similarly delay the regulation's effective date.
- [Gamification](#): The SEC is eyeing two separate rules to regulate digital engagement practices. [One for broker-dealers](#) and [one for investment advisers](#).
  - **Outlook:** The agency released an advanced notice of proposed rulemaking (ANPRM) for the former rule in September. Both were included as part of the previous UA and have had their timeline follow a congruent pattern with the SEC aiming to have notices of proposed rulemakings (NPRMs) released in April. This is a delay from the earlier target of October 2022 in the spring UA. Gensler has harped on gamification so it would be surprising if nothing gets done, but if there are further delays it may not be finalized on his watch.
- [Fund Disclosure](#): A major theme for Gensler at the SEC has been increasing transparency and he has proposed a number of new rules that would require new disclosures from the private funds it oversees.
  - **Outlook:** The agency has issued two proposals that would amend Form PF. Both have gone through their public comment periods and are not expected to be finalized before April, but with [the one](#) covering "All Filers and Large Hedge Fund Advisers" only wrapping up in October, it is likely that this will miss that timing. [The other](#) covering "Large Private Equity Advisers and Large Liquidity Fund Advisers," which concluded its comment period in March, has a more realistic chance to be done this spring. Gensler may opt to wait however and finalize both at the same time to only have to release a revised form once. The SEC also [included a rule](#) that would aim to require more disclosure by funds about their fees. Gensler has repeatedly made mention of this in public

appearances, but an NPRM is not expected until at least October.

- [Modernization of Beneficial Ownership Reporting](#): As part of its efforts to increase market transparency, the SEC is looking to cover the use of swaps.
  - **Outlook:** Driven by the lack of warning in the leadup to the Archegos collapse, the SEC [has proposed this rule](#), which includes an acceleration of the filing deadlines for beneficial ownership reports from 10 days to five days. It would also clarify when and how certain derivatives count towards the five percent threshold and the circumstances under which two or more persons have formed a “group” that would be subject to the reporting requirements. Ongoing negotiations may see this stripped down to just accelerate the filing deadlines as Gensler is struggling to find three votes for the rest of the provisions. Finalization of this rule is expected no sooner than April, the same timeline as last spring. This is not one of Gensler’s top priorities, but with most of the leg work done, it will likely be finished. April may be realistic as the comment period closed in April 2022.
- [Crypto](#): The only rules included in this UA with implications for digital assets are two from the SEC that do not directly regulate the industry.
  - **Outlook:** Gensler has made clear that his preferred approach for crypto is to rely on regulation by enforcement as he believes these assets are covered by existing rules. That said, [two rules](#) the SEC is looking to finalize have been flagged by stakeholders as having possible consequences on the industry, specifically exchanges and decentralized finance. These regulations are now not expected to be finished before April and with both having gone through their comment periods in the first half of last year, it is a possibility the agency will be close to that timeline.
- [SPACs](#): The SEC has [proposed new rules](#) aimed at increased disclosure of special purpose acquisition companies (SPACs).
  - **Outlook:** These rules would require additional disclosures about the SPAC’s sponsors, conflicts of interest, and sources of dilution. They would also address issues relating to projections made by SPACs and their target companies, including the safe harbor for forward-looking statements. The SEC is unlikely to finalize this rule before April, but with the comment period closing last June, it may not be far behind.
- [Basel III Capital Rule](#): The Federal Reserve, FDIC, and OCC are going to propose a rule that would revise the risk-based capital requirements for the largest and most complex US banks (referred to in the existing rules as Category I and Category II), as well as banking organizations with significant trading activity.
  - **Outlook:** These rules have been a longtime coming and although industry will lobby heavily to water them down, we do not expect that the Biden-appointed regulators, particularly Fed Vice Chair for Supervision Michael Barr, will show any appetite for carving them back from the initial proposal.

## Consumer Finance

The Consumer Financial Protection Bureau (CFPB) is expected to be one of the most prolific and aggressive of all of the Biden administration's regulators and the number of significant rulemakings that it is either going to finalize or propose in 2023 is indicative of this ambition. While some proposals have been well-telegraphed, others are less well-defined at this stage and could create major disruption if they are finalized with minimal changes.

- [Bank Overdraft Fees](#): The CFPB is going to propose a rule to Regulation Z that governs overdraft fees that consumers incur when their account is overdrawn. The rules would likely limit the amount of the fee and more specifically prescribe the circumstances in which such fees can be assessed, limiting their use and this fee as a revenue source for banks.
  - **Outlook:** The bureau does not have to modify its proposals in the face of opposition from Congress and industry and its lawyers expect to be sued for every proposal, so it instead focused on ensuring that its rules stand up to Administrative Procedures Act scrutiny, while still accomplishing the progressive goals of the bureau. Finalizing this rule as it is expected to be written would curtail the use of late fees and reduce such revenue to the largest banks.
- [Fair Credit Reporting Act \(Credit Bureau Reform\) Rule](#): The Fair Credit Reporting Act is a law designed to ensure fair and accurate credit reporting, among other uses. Codified in Regulation V, the law imposes legal duties on consumer reporting agencies as well as the providers and users of this information.
  - **Outlook:** Credit bureaus are one of the most complained about subsectors in consumer finance and the CFPB recently released a report detailing ongoing concerns about the business practices of the three biggest players. Although new rules from the CFPB would impose substantial new costs, they would also erect new barriers to entry on companies in this sector and these would likely insulate the three incumbents from new competition and further cement their place in the consumer finance ecosystem.
- [“Open Banking” Rule Governing Personal Financial Data](#): Section 1033 of the Dodd-Frank Act provides that covered entities must make available to consumers, upon request, transaction data and other information concerning a consumer financial product or service that the consumer obtains from the covered entity. This is meant to give consumers greater control over their financial information. The bureau is taking this one step further, and is trying to use this rule to create a new system of “open banking” where consumers can more seamlessly swap financial providers and competition can increase based on quality of service by reducing barriers to switching providers. The CFPB's next step in the rulemaking is to convene a SBREFA (small business advisory) panel and issue a report summarizing feedback received from the panel.

- **Outlook:** This is perhaps the CFPB rule that could be the most far-reaching, but also has the most unknowns surrounding how it is adopted and its eventual impact. CFPB Director Rohit Chopra has publicly argued that it will be transformative and increase competition, but there has been very little direct lobbying and engagement by industry on this rule, compared to others related to fee income, for example, because it is hard to quantify what, if any, impact this will have on revenue over time. **One interesting note on this rule is that we do not believe it would necessarily fall afoul of a future Republican leader of the bureau if Chopra was to be fired in 2025 if Democrats lost control of the White House. That gives the rule a unique staying power, compared to others.**
- [Not Sufficient Funds \(NSF\) Rule](#): If a consumer's transaction exceeds his or her account balance, the financial institution can pay the transaction and charge an overdraft fee, or it can decline the transaction and charge another fee for not having sufficient funds. Some institutions have begun to voluntarily drop these fees, but they still remain significant sources of revenue for many banks. The bureau would look to impose new limits or potentially ban NSF fees under this rulemaking.
  - **Outlook:** As with all of the fee rules, there is nothing stopping the CFPB in trying to finalize its proposals and the fact that many of the largest financial institutions have already dropped their NSF fees will only bolster the bureau's case that they are unfair and unnecessary.
- [Credit Card Late Fee Rule](#): The CARD Act created a safe harbor for card issuers to charge late fees that were "reasonable and proportional" or fell under the safe harbor created by the Federal Reserve Board during implementation of the law. The CFPB is going to amend the Fed's rules to change the calculation of the safe harbor to lower the amount of money that can be charged for a late fee. On June 22nd, 2022, the bureau issued an ANPRM seeking information from credit card issuers, consumer groups, and the public regarding credit card late fees and late payments, and card issuers' revenue and expenses and the next step is issuing a proposed rule.
  - **Outlook:** This change to the formula for determining the allowable late fee that a credit card company can charge is the most far-reaching of all the fee-related rulemakings and, for certain subprime issuers, this is an enormous source of revenue that will be hard to replace. The CFPB is in early stages of this rule compared to others, but we expect that it will be a high priority to be finalized well before it could potentially be repealed via the Congressional Review Act should Republicans sweep to unified control of government in the 2024 elections.
- [Small Business Lending Rule](#): Section 1071 of the Dodd-Frank Act amended the Equal Credit Opportunity Act to require financial institutions to report information concerning credit applications made by women-owned, minority-owned, and small businesses. In September 2020, the bureau outlined a proposal for a SBREFA panel and it convened in October 2020. The panel's report was completed and released in

December 2020. On October 8th, 2021, a NPRM was published in the Federal Register and the next action will be issuing the final rule.

- **Outlook:** This rule has been in the works for several years and although it is widely opposed by the financial industry, it is not expected to be changed significantly. The rule itself is not expected to cause changes to business practices of lenders, but if it is used to force portfolio analyses based on gender and race and concomitant enforcement actions for discrimination, then it could have an enormous impact on future lending.
- [Unfair or Deceptive Fees Trade Regulation Rule](#): This rule from the Federal Trade Commission (FTC) aims to address the “junk fees” that are not covered by the CFPB’s rulemaking procedure.
  - **Outlook:** The [FTC released](#) an ANPRM last fall and the comment period on that just closed. Addressing these fees has become a whole-of-government effort and it would not be surprising if other agencies propose similar rules. The FTC’s effort is targeting three specific types of fees, including fees that consumers have no way of opting out of. Given that this was only an ANPRM, the finalization of this rule will likely run into 2024. If this is to be the timeline, the agency will likely have to issue a NPRM this year, likely in late Q2 or early Q3.

## Energy & Environment

With control of Congress divided, the Biden administration will redouble its focus on its environmental regulatory agenda now that there is no viable path forward for a partisan legislative agenda. The Environmental Protection Agency (EPA) is responsible for the bulk of the White House’s efforts to address climate change, but rulemaking on climate, the environment, and energy is divided among multiple federal agencies including the Department of the Interior (DOI) and Council on Environmental Quality (CEQ). The Biden administration is pursuing other environmental rules in addition to those outlined here, including the Department of Energy’s ongoing initiative to tighten energy efficiency standards. Though the Inflation Reduction Act included language to formally give the EPA authority to regulate greenhouse gas emissions, the issue at hand is the recent *West Virginia v. EPA* Supreme Court case, as the Court’s invocation of the “major questions doctrine” in that case could facilitate legal challenges to other environmental regulations.

- [Power Plant Emissions](#): This rule would regulate emissions at power plants and is intended to replace the Obama administration’s Clean Power Plan and the Trump administration’s Affordable Clean Energy Rule.
  - **Outlook:** The UA estimates that an NPRM for this rule will be released in April 2023, a delay from the previous UA’s estimate of March. The UA notes that the EPA is reviewing the ramifications of the *West Virginia* ruling for this rulemaking. The UA predicts that this rule will not be finalized before June 2024, only months before the next presidential election and six months before the end of Biden’s first term. If the timeline is pushed back further, that could leave the rule vulnerable to being reversed by a potential future Republican

president or Congress.

- [PFAS](#): This rule would designate the PFAS chemicals PFOA and PFOS as hazardous substances under Superfund, which would trigger requirements for companies involved in producing, using, or transporting PFAS to pay for cleanup. This is expected to generate considerable headline risk.
  - **Outlook:** The Biden administration announced in its October 2021 [PFAS Strategic Roadmap](#) that the EPA would move forward with an NPRM on PFAS designation in Spring 2022. The agency ultimately [released](#) an NPRM in September 2022, a significant delay from the original timeline. This edition of the UA estimates that a final rule will be released in August 2023. The significant ramifications of Superfund designation for PFAS – for the EPA’s administrative capacity and for businesses – may be introducing delays to the process.
- [Renewable Fuel Standard](#): This rule would establish blending requirements for fuel. 2023 is the first year that Congress will not provide statutorily mandated blending volume requirements. The process for determining these requirements is now the responsibility of the EPA.
  - **Outlook:** The new blending requirements are noteworthy for the oil refining and biofuel industries. The EPA [released](#) an NPRM on the renewable fuel standard two weeks ago and the public comment period is scheduled to close on February 10th. The agency is holding a public hearing on the proposal today, January 10th, 2023. The UA estimates that a final rule will not be released before June 2023.
- [National Environmental Policy Act \(NEPA\)](#): The CEQ is now in the second phase of reviewing its regulations implementing NEPA in line with President Biden’s executive orders on climate.
  - **Outlook:** The timeline for this rulemaking is delayed. The previous UA estimated that an NPRM would be released in August 2022, while this edition of the UA estimates that it could come as soon as this month. In considering changes to NEPA implementation, the Biden administration may have to contend with a desire to promote environmental justice and public participation on one hand with calls to speed up the federal permitting process for infrastructure projects on the other hand.
- [Leasing Federal Land for Fossil Fuel Production](#): Through this rulemaking, the DOI intends to “update the fees, rents, royalties, and bonding requirements related to oil and gas leasing, development, and production” in response to a Biden executive order on climate.
  - **Outlook:** This rulemaking could raise the costs of oil and gas extraction on federal lands, but the timeline is delayed. The previous UA estimated that an NPRM would be released this month, but that target has shifted to April 2023 in the latest edition. Under the terms of the Inflation Reduction Act, permitting for renewable energy projects is paired with requirements for oil and gas

leasing. The Bureau of Land Management in late November [unveiled memoranda](#) implementing the law that concentrates drilling in areas where it already occurs and adds administrative requirements.

## Data Privacy

Privacy has been a topic of increasing focus for the FTC in recent months. In [remarks](#) delivered at the National Advertising Division Annual Conference in September, FTC Commissioner Alvaro Bedoya (D) described privacy as “a basic, vital necessity” and emphasized the need not only to address data collection practices but also the use and processing of Americans’ personal information. In July, President Biden in his [executive order on abortion access](#) called on the FTC “to protect consumers’ privacy when seeking information about and provision of reproductive healthcare services.” Soon after, the commission published a [blog post](#) focused on the enforcement of federal law regarding sensitive data, including location and health information. In August, the FTC [sued](#) Kochava, a data broker, for selling sensitive geolocation data.

- [Trade Regulation Rule on Commercial Surveillance](#): This wide-ranging rule is intended to “limit privacy abuses, curb lax security practices, and ensure that algorithmic decision-making does not result in unlawful discrimination.”
  - **Outlook:** The FTC [released](#) an ANPRM in August. The public comment period for this rule was originally scheduled to end in October but was extended to November 21st. According to a [fact sheet](#) released by the FTC, some specific areas of interest for the agency include inadequate data security practices, the impact of commercial surveillance on children, consumer-unfriendly data collection practices, inaccurate and discriminatory effects of algorithms, and dark patterns. The commission received over 12,000 public comments, and all will have to be reviewed before an NPRM is released. This rulemaking will likely stretch into 2024.
- [Children’s Privacy Protection Act Rule](#): The FTC continues to review public comments submitted in 2019 on its rule implementing the Children’s Online Privacy Protection Act (COPPA).
  - **Outlook:** While the commercial surveillance rule encountered opposition from the Republicans on the commission, children’s privacy has been a more bipartisan topic for the FTC. In May, FTC commissioners unanimously approved a new [policy statement](#) on the agency’s enforcement of COPPA relating to education technology that delineates prohibitions on collecting children’s personal information when using education tech services.

## Labor Policy

Biden has portrayed himself as a champion of the labor movement and has promised to be “the most-pro union president” in history. Under his presidency, the Department of Labor (DOL), FTC, and National Labor Relations Board (NLRB) have initiated several notable

rulemakings that would strengthen labor's hand against management. When governing, however, Biden has had to balance his support of workers with the need to prevent supply chain problems that could worsen inflation. The failure of some rail unions to ratify a contract agreement mediated by the White House last year, requiring Congress to pass legislation in December staving off a freight rail strike, has challenged Biden's pro-labor reputation. This year will offer the White House an opportunity to burnish its credentials with the labor movement through regulatory actions ahead of the 2024 presidential election.

- [DOL Worker Classification Rule](#): This rule would repeal a Trump-era standard on worker classification and replace it with a new test that would likely tighten companies' ability to classify workers as independent contractors.
  - **Outlook:** The DOL's Wage and Hour Division (WHD) [released](#) an NPRM in October. The public comment period was originally expected to close in November but the deadline was extended to December 13th. WHD staff will now need to review the input received, which numbers over 55,000 comments, before finalizing the rule. The UA estimates that the final rule will be released before May 2023. A final rule will likely face legal challenges. Companies whose business model would be most heavily affected by the change in DOL policy include **Uber (UBER)**, **Lyft (LYFT)**, and **DoorDash (DASH)**.
- [Covenants Not to Compete Rule](#): If finalized, this rule from the FTC would effectively ban non-compete clauses for workers.
  - **Outlook:** After being included for the first time, the FTC initiated its rulemaking process last week with [the release](#) of a NPRM. This was one of the rules that were included in President Biden's [executive order on competition policy](#) from July 2021, which increases our confidence that FTC Chair Lina Khan will view this as one of her top priorities for her regulatory agenda. **The rule is also notable for the FTC's assertion that Section 5 of the FTC Act gives it the authority to regulate noncompete agreements as they "constitute an unfair method of competition."** This is the same authority the agency is using to regulate data privacy. The rule will likely face legal challenges, but if upheld could have significant implications for the FTC's future rulemaking authority.
- [NLRB Joint Employer Rule](#): This rule would reverse a Trump-era rule by lowering the threshold to classify joint employers by taking into account whether employers have direct and/or indirect control over employees. The previous rule, passed in 2020, considered only whether an employer had direct control.
  - **Outlook:** The new rule risks increasing companies' liability for breaches of federal labor laws by franchise operators or contractors. The NLRB [released](#) an NPRM in September. The public comment period was originally scheduled to end in November, and it was extended until December 7th. Agency staff will next have to review nearly 13,000 comments received. The UA estimates that the rule will not be finalized before August 2023.

## Healthcare

The Department of Health and Human Services and the agency that governs Medicare and Medicaid, the Centers for Medicare and Medicaid Services (CMS), will have a busy 2023 implementing the Inflation Reduction Act and its drug pricing negotiation provisions, as well as several Biden administration priorities such as nursing home staffing scrutiny and new demonstrations from the Center for Medicare and Medicaid Innovation that look to increase racial equity and push providers further towards value-based care.

- [Drug Pricing Negotiations](#): This new proposal is perhaps the most far-reaching one that is NOT included in the UA but arguably could have been.
  - **Outlook:** CMS has said that it intends to set up the 95-person negotiating office and create its new rules and processes via guidance, rather than the more formal and legally secure notice and comment rulemaking process. Since it is only issuing guidance, these policies can easily be changed by a future administration, but it is also easier to roll it out quickly which is what is needed when the Biden administration is creating this new policy making entity from scratch.
  
- [Skilled-Nursing Facility \(Nursing Home\) CY24 Payment Rule](#): Typically, this is an annual proposed rule that updates the payment amounts and associated other regulations governing skilled-nursing facilities (SNFs) or nursing homes. For this year's proposal (CY24), there will be an added element which will be the new minimum staffing requirements that every facility will have to adhere to in order to continue receiving Medicare and Medicaid payments.
  - **Outlook:** The Biden administration has indicated that it would [publish a study on nursing home staffing numbers](#) prior to finalizing a rule on the issue. For this reason, we expect the study to come out in the first half of the year and that could spook investors and nursing home operators due to the increased costs that it would require. There simply are not enough active registered nurses to dramatically increase headcount at nursing homes as well as maintain them in hospital settings. 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.
  
- [Alternative Payment Model](#): This potential rule would create a new mandatory Medicare payment model under section 1115A of the Social Security Act. The purpose of the model is to save money for Medicare while “preserving or enhancing” quality of care for beneficiaries. If the model is deemed to be successful, then it can become a permanent and mandatory policy nationwide.
  - **Outlook:** It is unclear what the topic of the model will be, but there is a reasonable chance that it is focused on value-based care or combining value-based care and prescription drug pricing reforms and that it could be one of the Biden administration's most important healthcare-focused actions to date.

This type of proposal would add an overlay of value-based care features on top of all Medicare beneficiary doctor/patient relationships and it could be mandatory for all participating doctors. If this is in fact the topic of the model, it will be quite controversial, but there is nothing to stop the Biden administration from pushing it through if they have the political stomach for any blowback.

- [Medicare Advantage and Medicare Prescription Drug Benefit Program Payment Policy](#): This proposed rule is CMS's attempt to codify several Medicare Advantage and Part D payment policies that are outside the scope of the annual Advance Notice/Rate Announcement. The UA does not go into further detail about what those policies may be.
  - **Outlook:** As with any CMS regulation, the only thing that stops a regulation from being implemented as proposed (aside from not adhering to the strict rules of the Administrative Procedures Act) is a lack of political will, so we expect that with an election ahead in 2024, the Biden administration will be doing all it can to finalize any drug pricing agenda items once this is released.

## Tobacco

Under Biden, the Food and Drug Administration (FDA) is bringing the hammer down on the tobacco industry through several major rulemakings. This aggressive regulatory posture aligns with the White House's [Cancer Moonshot](#) initiative, which aims to reduce the cancer death rate by half in 25 years.

- [Ban on Menthol Cigarettes](#): This proposed rule would block menthol-flavored cigarettes from the US market.
  - **Outlook:** The end of the public comment period for the proposed menthol ban was extended from July to August. Over 175,000 comments were received and will have to be reviewed by FDA staff before the rule is finalized. The UA estimates that a final rule will not be released before August 2023. The tobacco industry is expected to seek to challenge the rule through lobbying and litigation.
- [Ban on Characterizing Flavors in Cigars](#): This proposed rule would block cigars with characterizing flavors other than tobacco (e.g., menthol, fruit, and cocoa) from the US market.
  - **Outlook:** As with the menthol cigarette ban, the flavored cigar ban saw an extension to the public comment period and is estimated to be finalized in August 2023.
- [Lower Nicotine Tobacco Product Standard](#): This proposed rule would lower the nicotine content in cigarettes to minimally or nonaddictive levels.
  - **Outlook:** This edition of the UA estimates that the FDA will not release a NPRM on a lower nicotine level before October 2023. More than any other tobacco regulation, this one poses an existential risk for the industry. It faces a

long road to implementation due to expected litigation and may require a second Biden term for success.



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