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End-of-Term Regulatory Recap and 2021 Key Issues

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OVERVIEW

As 2021 begins, New York faces the most potential for change in the health care policy landscape since the passage of the Affordable Care Act. While some of this change will come from the Governor's office and the State legislature, at the federal level, the Biden Administration and Democratic congressional majorities also have multiple levers for pushing a robust health care agenda. The incoming administration has already begun to conduct a wholesale review of the Trump administration's regulatory moves over the past several months, and legislative efforts on a fifth COVID-19 relief package with further health care relief are underway.

This document provides a summary of where we stand—today—on key federal health care issues. It includes a list of Trump administration actions over the last several months, a (subjective) forecast of how the Biden administration may deal with each, and key policy areas to watch throughout 2021.

TRUMP ADMINISTRATION

Policy Recap

The Trump administration has promulgated a number of regulations, guidance, and initiatives in recent months, which may now be subject to change by Congress or the Biden Administration.

The Congressional Review Act (CRA) establishes a legislative process for Congress to nullify these and other rules with issuance dates back to approximately August 21, 2020. However, the tight legislative calendar (among other factors) means that Democrats will likely only be able to overturn a few of the previous administration's rules through the CRA and will need to work with Congress to identify the highest priority rules for reversal. Most of them likely will not be related to health care.

The Biden Administration has also already issued a regulatory freeze to pause any Trump actions that have not yet gone into effect and impose a moratorium on further rulemaking across federal agencies. The Administration has various options to amend or rescind these actions, depending on their status:

- Rules being proposed and proposed rules that are not yet final have been *halted* per the regulatory freeze (noted as **halted** in the table below).
- For final rules that have not yet gone into effect, the Administration has directed federal agencies to consider *postponing the effective date* (noted as **postponed**) to March 21st and opening a new 30-day comment period.
- For *final rules that have taken effect* (noted as **in effect**), the Biden administration would generally need to utilize the formal notice and comment rulemaking process to make changes.

Some of the Trump administration's recent actions are likely to stand in large part, though potentially with some modification. For example, the Biden administration may wish to make minor changes to some rules, such as to add consumer protections, or stakeholders may raise legal challenges to the substance of the regulation or procedural challenges to the Trump administration's hurried rulemaking process, but the Biden administration might reimplement related regulations. However, other regulatory actions are unlikely to stand, either because the Biden administration will roll it back, Congress will act to invalidate it, or legal challenges will preclude implementation.

The below table includes an initial assessment of where the rules, regulations, guidance, and initiatives promulgated in the last few months by the Department of Health and Human Services (HHS) and/or the Centers for Medicare and Medicaid Services (CMS) currently stand, including the current status and originally proposed effective dates of each action.

Initiative	Brief Description	Current Status	Original Proposed Effective Dates	Forecast
Direct Contracting Geographic Model	Model participants would coordinate care and be responsible for the clinical outcomes of Medicare beneficiaries across their geographic region.	RFA Issued	Application period: 3/1/2021 – 4/2/2021 Model period: 1/1/2022 – 12/31/2024	Likely to proceed, although with delays and measurable modifications
DC Medicaid Managed Care Organization (MCO) Option	MCOs may participate as Direct Contracting Entities (DCEs) under the Professional and Global Direct Contracting Options. Model participants would coordinate care for beneficiaries dually eligible for Medicare and Medicaid.	Announced RFA expected with reopened DC application period	Application period: Spring 2021 Model period: 1/1/2022 – 12/31/2026	Likely to proceed in some form
Stark Law and Anti-Kickback Statute (AKS) Final Rules	These rules modify existing physician self-referral and anti-kickback rules to provide a framework to protect value-based arrangements between physicians and/or other providers that aim to coordinate care, improve care quality, and reduce cost through, e.g., volume-based reimbursement or offering beneficiary incentives.	In effect Subject to challenge due to GAO ruling under CRA that required 60-day delay has not been met.	Effective date: Stated as 1/19/2021 Subject to challenge due to GAO ruling	Likely to proceed, with possible delays or revisions
Transparency in Coverage Final Rule	This rule requires insurers to publish negotiated rate information beginning January 1, 2022, and, the following year, provide personalized out-of-pocket costs and negotiated rates for 500 "shoppable" services. This personalized information must be provided for all covered items and services beginning in 2024.	In effect	Effective date: 1/11/2021	Likely to continue
HIPAA Privacy Rule Modernization Proposed Rule	This rule would change regulations implementing the Health Insurance Portability and Accountability Act (HIPAA) in order to improve patient access to health information, improve care coordination and case management, and more.	Halted	Comments due: 3/22/2021	Likely to continue in regular rulemaking, subject to public comment

Initiative	Brief Description	Current Status	Original Proposed Effective Dates	Forecast
Medicaid Value-Based Purchasing for Prescription Drugs Final Rule	This final rule aims to encourage drug manufacturers to enter into value-based payments arrangements with states and commercial payers by revising the average manufacturer price and "best price" reporting requirements under the Medicaid Drug Rebate Program. The rule also creates minimum standards in state Medicaid Drug Utilization Review programs to reduce opioid-related fraud, misuse, and abuse.	Postponed	Original effective date: 3/1/2021	Likely to continue in some form
Prior Authorization and Patient Access to Health Information Proposed Rule	This rule aims to improve health information exchange by increasing access to patient-specific payer data and streamlining the prior authorization process (detailed further below in this document).	Halted and/or postponed	Final rule: Announced 1/15/2021 The final rule was not published in the Federal Register and the announcement was removed from the CMS website.	May proceed with modifications. However, stakeholders may raise procedural challenges due to the lack of an adequate notice period.
Medicare Part B Most Favored Nation Pilot	This program would implement a seven-year, mandatory, nationwide demonstration model to tie reimbursement for the 50 Part B drugs with the highest annual spending to the lowest price paid by a cohort of counties in the Organisation for Economic Cooperation and Development (OECD).	Postponed and stayed	Comments due: 1/26/2021 Effective date: 1/1/2021 Stayed by Maryland District Court pending legal action	Unlikely to proceed as proposed
Point-of Sale Prescription Drug Rebates Final Rule	This rule would remove the AKS safe harbor for prescription drug rebates provided by manufacturers directly to pharmacy benefit managers (PBMs) and health plans and create two new safe harbors for point-of-sale discounts provided directly to patients and for flat fees paid by drug companies directly to PBMs.	Postponed Subject to challenge due to GAO ruling under CRA that required 60-day delay has not been met.	Effective date: 1/29/2021	Unlikely to proceed as proposed
Final Rule on Religious Liberty Protections for Grantees	Under this final rule, faith-based organizations are not required to notify clients in advance of their religious character or of any services they do not provide for religious reasons, nor must they refer clients to alternative providers.	Postponed	Effective date: 2/1/2021	Unlikely to proceed

Initiative	Brief Description	Current Status	Original Proposed Effective Dates	Forecast
2022 Final Notice of Benefit and Payment Parameters for Marketplace Plans	The final rule addresses a subset of the provisions in the proposed rule, including codification of 2018 "State Relief and Empowerment Waivers" guidance to broaden interpretation of the substantive "guardrails" Section 1332 waiver applications must meet and a process for states to transition away from a centralized marketplace to decentralized enrollment through insurers and web-brokers.	Postponed	Effective date: 3/15/2021	Unlikely to proceed as proposed
Final Rule on HHS Guidance Documents	This rule would place new requirements on guidance documents issued by HHS. The rule is designed to limit the ability of HHS' agencies to use guidance to circumvent the rulemaking process and, notably, requires "significant guidance documents" to be published in the Federal Register for notice and comment before taking effect.	In effect	Effective date: 1/6/2021	Likely to be withdrawn by the Biden Administration
Automatic Sunset of HHS Regulations Final Rule	This rule would automatically sunset HHS regulations after ten years unless they undergo agency review. Specifically, the rule requires HHS to review all regulations that have a significant economic impact upon a substantial number of small entities every ten years and to assess every regulation, with some exceptions, every ten years, or else they would expire.	Postponed	Effective date: 3/22/2021	Unlikely to proceed as proposed Could be a target for CRA disapproval
Notice on Public Access to Impact Analysis Materials	This policy would require HHS to publicly post all impact analysis materials associated with a rule or demonstration project at the time the results of the impact analysis are made public.	In effect	Effective date: 11/30/2020	Likely to be rescinded by the Biden Administration

Additionally, some annual rules were finalized on their usual regulatory timeline, but because that occurred during the end of a presidential term, they may receive another look from the Biden administration. Because these rules took effect January 1, 2021, another round of formal rulemaking, including notice and comment periods, is required to make changes. While this may be possible for policy changes being phased in in later years, for example, it seems unlikely that the incoming Administration would retroactively change operational provisions already in effect. These rules may include:

- The Contract Year 2022 Medicare Advantage and Part D final rule and rate announcement;
- The Calendar Year 2021 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System final rule; and
- The Calendar Year 2021 Medicare Physician Fee Schedule final rule.

BIDEN ADMINISTRATION

Key Issues for 2021

In addition to COVID-19 legislation—currently under discussion as the Biden administration's first legislative effort—we expect other Administration priorities to include:

1. Equity

President Biden signed 15 Executive Orders within hours of his inauguration on January 20th. They included a clear focus on equity, including the establishment of a COVID-19 Health Equity Task Force, a "Whole of Government" initiative to embed equity across federal policymaking, and rescinding the Trump Executive Order limiting the ability of federal government agencies, contractors, and grantees to implement diversity and inclusion training. Further actions are planned in the coming weeks.

Democrats on the House Committee on Ways and Means also recently released a framework and a report, which offer a guide to their plans for work on health and economic equity in the 117th Congress. One of the four equity pillars laid out by the Committee included "affordable, comprehensive, and accessible health care," which focuses on, among other items:

- Telehealth access for underserved communities;
- Innovation models that expand health services;
- Health plan benefits that address social determinants;
- Closing coverage gaps; and
- Fair prescription drug prices.

2. ACA

Major changes to the Affordable Care Act are unlikely over the next several years, but the Biden Administration will likely seek undo the effects of the Trump Administration's hostile approach to the law, and, where possible, build on the ACA to enroll more Americans in affordable, ACA-compliant health coverage. These changes may include:

- Restoring marketplace advertising funding, which Trump cut by as much as 85%;
- Rolling back expansion of short-term, limited duration health plans and association health plans which do not meet ACA requirements;
- Creating a special enrollment period through regulatory action under the public health emergency declaration;
- Increasing premium subsidies;
- Making Medicaid expansion more attractive in non-expansion states;
- Reinstating the ACA birth control coverage requirements; and
- Issuing new rulemaking to reverse Trump's Title X final rule, which prohibited health care providers that receive Title X funding from performing or referring for abortions.

3. Medicaid Program and State Waivers

The Trump administration approved several controversial Medicaid waivers in its final months. The most high-profile of these was Tennessee's, a ten-year agreement under which the State will receive Medicaid funding as a spending-capped block grant. The Trump administration also limited the Biden administration's ability to reverse such waivers, asking states to sign contracts pledging that CMS would not end a waiver with fewer than nine months' notice.

Despite this, the Biden Administration is likely to work towards reversing such waivers, given Democrats' opposition to provisions like block grants and work requirements. Given that no CMS Administrator has been announced, the Administration's overall waiver philosophy is unknown as of yet. Possible directions include moving back to models that look more like the previous Delivery System Reform Incentive Payment (DSRIP) model—pushing coordination between providers and overall quality and value-based payment goals—or could potentially be more ambitious, looking towards waivers like the Maryland Total Cost of Care Model, incorporating systemwide cost controls.

The Biden Administration is also likely to stop legal defenses of the Trump Administration's August 2019 "Public Charge rule," which dramatically broadened the definition of a "public charge" for immigration and visa denial purposes, discouraging the receipt of Medicaid. It may begin a rulemaking process to either roll back the definition to pre-Trump standards or develop a new definition, though ongoing litigation could complicate the rulemaking process, as the Seventh Circuit has issued a stay that has allowed the rule to continue being implemented.

4. Drug Pricing

The Trump Administration's late-breaking initiatives on drug pricing—particularly the Part B Most Favored Nation model—are likely to be overturned or rolled back by the Biden Administration. However, the issue of implementing controls on prescription drug pricing will not go away. Like price transparency, this issue is popular with voters and widely considered pro-consumer by policymakers. While comprehensive or significant progressive legislation is unlikely to pass, a limited and/or bipartisan compromise bill, such as the bipartisan proposal approved by the Senate Finance Committee in 2019, might have a chance.

One notable recent action in this area was the Trump Administration's final rule on Medicaid value-based purchasing. It is built upon the Medicaid "best price" rule, which established that Medicaid beneficiaries should receive a rebate from pharmaceutical manufacturers. The final rule seeks to leave room for more innovative arrangements under value-based purchasing models by broadening the definition of value-based purchasing, easing reporting requirements, and allowing pharmaceutical manufacturers to offer more than one "best price". The Biden Administration's regulatory freeze implies that the rule will be delayed through March 21st while the Administration reviews the rule and considers whether to continue or modify it.

5. Value-Based Payment

The Trump Administration largely continued the federal march away from fee-for-service and towards value-based care through its work at CMS, and specifically at the Innovation Center (CMMI). The Biden administration is very likely to continue this work, including through the current Direct Contracting (DC) initiative. The DC model offers new opportunities for provider organizations to participate in risk-sharing payment arrangements that cover the Medicare fee-for-service (FFS) population. Some aspects of the Direct Contracting model are very likely to be delayed and/or revised under the Biden administration, but likely in a limited way. The pending announcement of new CMS and CMMI leadership will undoubtedly provide more insights into plans for these offices.

One Trump administration midnight rule is particularly relevant here: changes made to Stark and Anti-Kickback enforcement (as described above) opened up space for value-based collaborations between providers. The new adjustments allow exceptions from the rules for organizations taking full or substantial risk, and who seek to coordinate, manage, and improve quality of care for a target patient population, reduce costs for payers without reducing quality, and transition from volume-based mechanisms of payment and delivery to quality and value-based mechanisms.

6. Telehealth

New telehealth flexibilities have revolutionized care delivery during the COVID-19 pandemic, with telehealth still accounting for nearly 20% of physician visits nationwide in early December 2020. But many of these flexibilities will expire no later than at the end of the calendar year in which the COVID-19 Public Health Emergency (PHE) expires.

The Biden Administration has announced that the PHE will continue through at least the end of 2021. However, once it ends (whether in 2021 or later) a permanent legislative expansion may be more difficult to achieve than currently imagined. Legislation will have to contend with the Congressional Budget Office's scoring of telehealth proposals—which has historically projected large resulting increases in spending—as well as policymakers' concerns about the potential for fraud. Specifically, policymakers need to grapple with issues such as:

- Whether to continue requiring a prior in-person relationship between practitioner and patient;
- Effects of the removal of geographic and originating site barriers;
- Ensuring adequate reimbursement for Federally Qualified Health Clinics (FQHCs) and Rural Health Clinics (RHCs); and
- Possible hindrances to access due to lack of broadband availability.

7. Price Transparency

The Trump administration established requirements for both hospitals and insurers to publish "real" rates, including hospitals' payer-specific negotiated charges and plans' negotiated rates with in-network providers, as part of its price transparency initiatives. The Biden administration is not expected to reverse these initiatives, but it may change the approach.

The first set of requirements (for providers only) went into effect on January 1st, after an appeals court rejected hospitals' challenge on December 29th. Provider compliance has been slow; CMS has announced that it plans to begin a sample of audits in January, with a potential $300 per day civil monetary penalty. While the AHA has urged the Biden Administration to review the rule, price transparency policies will continue to have traction in Washington. Such policies are broadly accepted in federal health policy debates as pro-consumer and popular with voters, regardless of how such provisions function to help consumers in the real world.

8. Antitrust Enforcement

Given HHS Secretary nominee Xavier Becerra's role leading a major antitrust lawsuit in California, the Biden administration is expected to increase scrutiny of proposed health system mergers and of possible anticompetitive actions by organizations with a dominant market share. This may feel less urgent today, given how many health systems paused or abandoned merger and acquisition plans in 2020. Annual deal volume is still at an 11-year low, down 25% against the 10-year average, but hospital merger and acquisition activity rebounded in the fourth quarter of 2020, with 28 deals announced.

Some possible actions already began under the Trump administration. On January 13th, the Federal Trade Commission (FTC) ordered six major health insurers to provide claims data so they could study the impact of physician consolidation. Specifically, FTC requested patient-level commercial claims data for inpatient, outpatient, and physician services in 15 states from 2015 through 2020. This request is part of FTC's restructuring of its Merger Retrospective Program, which is intended to test its analytical tools, strengthen enforcement efforts, and determine whether its threshold for bringing an enforcement action in a merger case has been too permissive.

9. Surprise Billing

In December, Congress passed long-debated surprise billing legislation as part of its omnibus spending bill. While 17 states, including New York, had already adopted comprehensive surprise billing legislation, the federal legislation extended protections to individuals covered by employer self-funded plans, as well as to those individuals in states without comprehensive laws.

This legislation will take effect in 2022, raising the question of how it will interact with the existing state laws interact. In general, where state law is stronger than the federal floor, state laws prevail. However, in many states, this could result in a patchwork of regulations, leaving some consumers under the jurisdiction of the federal law, and others under state law. In response, states may adjust their own policies to be consistent with federal law. The Biden administration will also need to work to implement the legislation by establishing a list of eligible arbitrators, helping to determine what factors will guide arbitrators' decisions, and nailing down the details of reporting requirements.

10. Interoperability and APIs

As required by the 21st Century Cures Act, the Trump Administration issued various rules to promote interoperability. These have been relatively non-controversial and should create long-term opportunities for innovation. The main prongs include (1) prohibiting entities from engaging in "information blocking" activities (i.e., preventing patients from accessing their data) and (2) requiring regulated payers (Medicare, Medicaid/CHIP, and federal Marketplace issuers) to facilitate standardized access to their data through application programming interfaces (APIs). This includes a Patient Access API for plan-to-member data sharing and a public-facing Provider Directory API. Due to COVID-19, the effective dates for these two requirements have been delayed to April 5th and July 1st, respectively.

In December 2020, the Trump Administration proposed to create further health care data and prior authorization requirements for Medicaid/CHIP and federal Marketplace (but not Medicare) issuers. The proposed rule would add additional API requirements to (1) facilitate plan-to-plan and plan-to-provider data sharing and (2) to standardize prior authorizations by enabling document lookup and electronic transmission of requests. Patients would also have greater access to prior authorization information through the Patient Access API. If and when these requirements are fully implemented, they will create an opportunity to significantly streamline and enhance care coordination and care delivery processes.