Health Law Daily Wrap Up, STRATEGIC PERSPECTIVES: How has the regulatory freeze impacted health reform?, (Apr. 23, 2021)

Health Law Daily Wrap Up

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The Biden Administration has made little move to advance its health care agenda in its first three months, but has provided signals about future action while it reviews current regulations.

In a move typical for new presidents, the Biden Administration issued a regulatory freeze upon inauguration, asking agency heads to withdraw rules not yet published in the *Federal Register* and to consider delaying published rules' effective dates for 60 days. This regulatory freeze was intended to allow additional time for comment and review of "fact, law, and policy" related to those rules. Many health care rules fell under this regulatory freeze, but little has been said about them since. This silence, compounded by the lack of documents issued by HHS and CMS during the new administration, provides little indication of President Biden's plans for advancing his health care agenda. This Strategic Perspective reviews the health care rules impacted by the regulatory freeze.

When does a frozen rule thaw?

Although the regulatory freeze memorandum describes the process, there is a decided lack of clarity to the public on a rule's fate. The memorandum grants some discretion to agency leaders at least facially by using words such as "ask" and "consider" while outlining steps to delay the effective dates of issued rules for 60 days and opening a 30-day comment period. Additional delays beyond this period are mentioned as a possibility for rules needing more consideration. Two options are provided for the next step beyond the 60-day delay: (1) no further action taken for rules raising no substantial questions; or (2) notifying the director of the Office of Management and Budget (OMB) and "tak[ing] further appropriate action in consultation with the OMB Director."

The regulatory process, which is already unclear to the uninitiated, is make murkier by the lack of decisive action to indicate what has happened to a regulation in progress. There is no clear list of rules impacted by the freeze, no easy place to check on whether "no further action" was taken, no clarity on whether an agency head is working with the OMB Director to take "further appropriate action." Combing through the *Federal Register* to track delays is not a straight-forward process, and the delay of an effective date of a final rule might be published as a final or proposed rule. The most up to date, easily digestible information about the current status of rules is contained in HHS' semiannual regulatory update, issued March 31, 2021 (86 FR 16892).

In an interview with Wolters Kluwer, Jeffrey Davis, a senior attorney at Baker, Donelson, Bearman, Caldwell & Berkowitz, PC, expects the Biden Administration to reverse the Trump Administration's efforts to limit access to health care and HHS' powers. An Executive Order issued January 28, 2021, directed the Secretaries of HHS, Labor, and Treasury to review regulations and polices related to the ACA that would undermine access to health care. Davis mentioned Medicaid work requirements, block grants, and "actions taken by the prior administration to limit HHS's ability to implement health care programs through sub-regulatory guidance" as particular items of interest.

Impact on access to drugs and devices

Many of the recently finalized regulations impacted access to various drugs and devices through changes in reimbursement, authorizations, and approvals.

Part D drug authorization. A final rule issued December 31, 2020 (85 FR 86824) originally set to go into effect on February 2, 2021, amended the requirements for the electronic prescribing program for Part D. The rule required Part D plan sponsors to support a particular standard for prior authorizations in order to better facilitate

the prior authorization request and response between the prescriber and the plan sponsor. The effective date was delayed to March 30, 2021 (86 FR 7813).

Coverage of breakthrough devices. CMS established the Medicare Coverage of Innovative Technology (MCIT) to provide faster coverage for devices that receive the FDA's breakthrough designation. The rule (86 FR 2987) would have provided four years of national Medicare coverage either on the date the FDA authorized the device or starting within two years after on a date chosen by the manufacturer. CMS issued an interim final rule on March 17, 2021, (86 FR 14524) delaying the effective date until May 15, 2021, and soliciting comments on potential issues. CMS noted that the rule did not address operational issues related to covering devices, such as establishing payment and coding processes, which can be complicated if the device would be part of an existing bundled payment system. Other concerns include a potentially overlapping rule related to durable medical equipment (DME), a higher-than-expected volume of breakthrough devices, and the practical benefit to the Medicare population.

Insulin and epinephrine pricing. HHS has delayed a final rule (85 FR 83822) that would have required health centers participating in the 340B drug pricing program to ensure that they are providing insulin and injectable epinephrine at prices at or below the discounted price paid by the health center to patients that may have difficulty paying. HHS justified delaying the effective date of the rule to July 20, 2021 (86 FR 15423), by stating that such a delay would allow the agency and public health centers to prioritize work related to COVID-19 and maintaining the delivery of primary care services while considering questions raised about the implementation of the rule.

Rules involving reimbursement for government health care programs

Part C and D. A rule issued on January 19, 2021 (86 FR 5864), involving changes to Medicare Advantage, Medicare prescription drug programs (PDPs), seemingly escaped a delay of its effective date, perhaps because that effective date fell just after the 60-day period. The rule implemented sections of the Bipartisan Budget Act of 2018 (BBA) and Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) Act.

Organ procurement organizations. A final rule issued December 2, 2020 (85 FR 77898) revised the conditions for coverage for organ procurement organizations, which are requirements that the organizations must meet to qualify for payments from Medicare and Medicaid. The revisions sought to improve outcome measures by making them more objective, reliable, and transparent, as well as increase competition in the open donation service areas. The changes are intended to result in an increase in organ donation and transplantation. The original effective date of February 1, 2021 was delayed until March 30, 2021 with a 30-day comment period (86 FR 7814).

HIPAA privacy modifications

On March 9, 2021, the HHS Office for Civil Rights (OCR) extended the public comment period for the proposed changes to the Health Insurance Portability and Accountability Act (HIPAA) (P.L. 104-191) Privacy Rule. The proposed changes, originally published January 1, 2021 (86 FR 6446), center around improving patient access to their own health information and advancing care coordination between providers. These changes fall in line with the OCR's recent efforts to prevent information blocking. The comment period is extended to May 6, 2021 (86 FR 13683).

Court-ordered delays

Anti-kickback safe harbors. On November 30, 2020, HHS changed regulatory safe harbors to the anti-kickback statute (AKS) (42 U.S.C. §1320a-7). The final rule (85 FR 76666) defined certain terms and established three specific changes: (1) removed safe harbor protection for Part D plan sponsors receiving price reductions for drugs; (2) created a safe harbor for some point-of-sale reductions provided by manufacturers for Part D or certain Medicaid managed care organizations; and (3) created a safe harbor for fixed services fees paid to pharmacy benefit managers (PBMs) by manufacturers. The original effective date for most of the provisions

was to be January 29, 2021, with the effective date for the removal of safe harbor protections for Part D plan sponsors effective January 1, 2022.

The first 60-day delay on February 2, 2021, cited both the regulatory freeze and pending litigation challenging the rule (86 FR 6815), moving the effective date of the first regulations to go into effect to March 22, 2021. On February 19, 2021, HHS delayed the effective date of the removal of the safe harbor protection for Part D plan sponsor regulation by one year, to January 1, 2023, following a court order due to litigation challenging the rule (86 FR 10181). Then on March 22, 2021, HHS similarly delayed the effective date of the rest of the regulations to January 1, 2023, pursuant to a second court order (86 FR 15132).

SUNSET rule. The Securing Updated and Necessary Statutory Evaluations Timely (SUNSET) rule (86 FR 5694), published January 19, 2021 with an effective date of March 22, 2021, finalized regulations that started a timer on HHS regulations. With some exceptions, HHS regulations issued in titles 21, 42, and 45 would expire the later of (1) five years after the SUNSET rule's effective date; (2) 10 years after the year the regulation was first promulgated; or (3) 10 years after the latest year that HHS either assessed or reviewed the regulation.

On March 9, 2021, a number of groups filed suit in the Northern District of California alleging that the SUNSET rule was, among other things, arbitrary and capricious and threatened harm to the groups and the general public by causing regulatory confusion that would impede operations of providers. On March 23, 2021, HHS chose to delay the effective date of the rule due to the "interests of justice," as the agency believes that the allegations of harm are credible and that the claims may be found to have merit (86 FR 15404). HHS noted that finalizing the rule during litigation would cause confusion and could create compliance costs as entities planned for the rule's implementation. HHS stated that it would continue to evaluate the rule during the postponement.

Most favored nation model. Last year, CMS established the Most Favored Nation (MFN) payment model (85 FR 76180), which was created to bring prices for Part B drugs and biologics more in line with international prices in order to control spending growth. The model was intended to run for seven performance years starting January 1, 2021, and include an initial cohort of 50 drugs. The model would have required participation from all providers and suppliers. A California district court issued a preliminary injunction preventing HHS from implementing the MFN payment model on December 28, 2020. The court found that the parties challenging the rule are "virtually certain" to succeed on the claim that the Administrative Procedure Act's (APA) notice and comment requirements were violated when the rule was created, and would experience irreparable financial losses if the rule took effect.

Davis mentioned the challenge to the MFN model as just one of the many drug pricing actions the Trump Administration took that is receiving "considerable attention" from the industry, as many wonder how and whether the Biden Administration will change course on the topic. He noted that the administration's actions in this area may depend on what legislation, if any, Congress decides to enact. However, Davis believes that the Biden Administration is less likely to address or change the controversial hospital price transparency regulations, as this administration seems to also look favorably on transparency efforts.

Conclusion

The Biden Administration seems to be following a cautious path to health reform so far by taking time to assess current regulations and impediments to care. Although Davis believes that the ACA will be expanded, and that the efforts to improve and increase Medicaid coverage in the American Rescue Plan Act will be built upon through regulatory action, much remains to be seen. Many resources are still directed toward the COVID-19 public health emergency and will continue to be for the foreseeable future. Although the rollout is slow so far, the Biden Administration, still in its infancy, will undoubtedly have much more health reform to come.

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