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Biden Administration 60-day Regulatory Freeze

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On Wednesday, January 20, 2021, President Biden's chief of staff, Ronald A. Klain, circulated a memorandum (memo) to the heads of federal executive departments and agencies outlining an Executive Action implementing a 60-day freeze on any new or pending regulations. This is a customary practice for new administrations. The freeze allows the administration to conduct an appropriate review of these rules to determine if there is any conflict with the President's policy objectives. Both the Obama and Trump administrations issued nearly identical Executive Actions on their first day in office.

Regulatory Freeze Process

The memo directs that agencies do not issue or propose any new rules in any manner until a department head appointed by the President can review or approve the rule. The memo additionally directs that rules that have been sent to the Office of the Federal Register (OFR) but have not yet been published be immediately withdrawn.

For rules that have been published in the Federal Register or issued in any matter, but have not yet taken effect, the memo asks department heads to consider postponing the rules' effective dates for 60 days from the issuance of the memo "for the purpose of reviewing any questions of fact, law, and policy the rules may raise." If a department head elects to postpone the effective date of a regulation, the memo asks that a 30-day comment period be considered on the delayed rule. Additionally, the memo provides department heads discretion to extend the pause of the effective date past the recommended 60-day delay.

During the 60-day effective pause, if a rule raises no substantial questions of fact, law or policy, no further action is required. If a rule does raise a substantial question of fact, law or policy, the memo directs that the flagging agency coordinate with the Office of Management and Budget (OMB) to take the appropriate action.

Agency Actions Subject to the Regulatory Freeze

The memo applies to "any substantive action by an agency … that promulgates or is expected to lead to the promulgation of a final rule," and "any agency statement of general applicability and future effect that sets forth a policy on a statutory, regulatory, or technical issue." The Executive Action also provides for an exception for emergency situations relating to health, safety, environmental, financial or national security matters.

The memo has no effect on rules that have already taken effect prior to the January 20, 2021, noon deadline. For the administration to amend or repeal rules that have already gone into effect, the traditional notice-and-comment process would need to take place.

Notably, the memo concluded with a statement that Klain might amend the regulatory freeze process for any agency actions taken "to frustrate the purpose underlying this memorandum." In that case, Klain "may modify or extend this memorandum, pursuant to the direction of the President, to request that agency heads consider taking steps to address those actions." This statement makes it unclear if the regulatory freeze will extend to some last-minute Health and Human Services (HHS) regulations that were given emergency effect prior to January 20 due to the COVID-19 public health emergency, but would have normally been effective after the deadline, making them subject to the regulatory freeze.

The following is a list of regulations in the health and life science fields that the memo may affect:

Regulations Concerning Prescription Drugs and Medical Devices

- **PDM Model** – A request for applications (RFA) issued by Centers for Medicare & Medicaid Services (CMS) on January 19, 2021, from eligible Prescription Drug Plans (PDPs) and Medicare Advantage Organizations offering Medicare Advantage-Prescription Drug Plans (MA-PDs) to participate in the Part D Payment Modernization Model (PDM Model) for Contract Year (CY) 2022.
- **E-prescribing for Part D sponsors –** A final rule issued by CMS due to go into effect February 1, 2021, requiring Part D plan sponsors use a new transaction standard for the e-prescribing program to ensure secure electronic prior authorization request and response transmissions.

- **Medicare coverage of new devices –** A final rule issued by CMS due to go into effect on March 15, 2021, establishing the Medicare Coverage of Innovative Technology (MCIT) pathway, which allows certain devices to receive immediate Medicare coverage upon market authorization by the Food and Drug Administration (FDA).
- **Insulin pricing –** A final rule issued by CMS due to go into effect on January 22, 2021, requiring entities funded under Section 330(e) of the Public Health Service Act (PHS Act) to provide access to insulin and injectable epinephrine to low-income health center patients at the same price the health center purchased the drugs through the 340B Program. The Biden administration has already announced the effective date of this rule will be delayed until March 22, 2021.
- **VBP arrangements –** A final rule issued by CMS due to go into effect on March 1, 2021, which finalizes new and clarifies already existing regulatory policies to make it easier for states to participate in value-based purchasing arrangements (VBPs) with manufactures.
- **Discounts for prescription products** – A final rule issued by HHS due to go into effect on January 29, 2021, amending the safe harbor regulation concerning discounts by changing the definition of certain conduct that is protected from liability under the Federal anti-kickback statute (AKS) of the Social Security Act.

Regulations Concerning Health Programs

- **E-exchange of health care data –** A proposed rule published on December 18, 2020, by CMS, HHS and the Office of the National Coordinator for Health Technology (ONC) placing new requirements to improve the electronic exchange of health care data to make insurers' prior authorizations on medications more efficient on state Medicaid and CHIP fee-for-service (FFS) programs, Medicaid managed care plans, CHIP managed care entities and Qualified Health Plan (QHP) issuers on the Federally-facilitated Exchanges (FFEs).
- **AKS safe harbors** – A final rule amending the safe harbors to the federal AKS by adding new safe harbors and modifying existing safe harbors that protect certain payment practices and business arrangements from sanctions under the anti-kickback statute. This rule was due to go into effect on January 19, 2021. However, the Government Accountability Office (GAO) found that the effective date violated the Congressional Review Act (CRA), which requires major rules to have a 60-day delay in the effective date from the date of publication in the Federal Register. This finding will likely be used by the Biden administration to argue the rule is subject to the regulatory freeze memorandum.
- **Physician fee schedules** – A final rule issued on December 1, 2020, by CMS that went into effect on January 1, 2021, making changes to the physician fee schedule. The changes will raise Medicare payments to primary care doctors and specialists who rely on outpatient visits to care for their patients. Due to the public health emergency, CMS waived the normal 60-day effective delay for this rule. Because of the emergency early effective date for this rule, it is unclear if this final rule will be subject to the regulatory pause.
- **Physician self-referral regulations** – A final rule establishing exceptions to the physician self-referral law for certain value-based compensation arrangements between physicians, providers and suppliers. This rule was due to go into effect on January 19, 2021. However, the Government Accountability Office (GAO) found that the effective date violated the Congressional Review Act (CRA), which requires major rules to have a 60-day delay in the effective date from the date of publication in the Federal Register. This finding will likely be used by the Biden administration to argue the rule is subject to the regulatory freeze memorandum.
- **Medicare Advantage rates** – A rate announcement by CMS on January 15, 2021, "of the annual capitation rate for each Medicare Advantage ("MA") payment area for CY 2022 and the risk and other factors to be used in adjusting such rates."
- **Organ procurement** – A final rule due to go into effect on February 1, 2021, revising the outcome measures set forth in the Organ Procurement Organizations (OPOs) Conditions for Coverage (CfCs) in order to increase donation and transplantation rates.
- **Medicare outpatient payment system** – A final rule issued by CMS, published on December 29, 2020, and effective as of January 1, 2021, making changes to the amounts and factors used to determine the payment rates for Medicare services paid under the outpatient prospective payment system and those paid under the ambulatory surgical center payment system. The rule is intended to provide more flexibility in obtaining Medicare coverage if the hospital determines outpatient care is the best fit for its patient. Due to the public health emergency, CMS waived the normal 30 to 60-day effective delay for this rule. Because of the emergency early effective date for this rule, it is unclear if this final rule will be subject to the regulatory pause.
- **Grandfathered health plans** – A joint final rule issued by the IRS, HHS and the Department of Labor amending "current rules to provide greater flexibility for certain grandfathered health plans to make changes to certain types of fixed-amount cost-sharing requirements without causing a loss of grandfather status under the Patient Protection and Affordable Care Act." The rule is effective as of January 14, 2021, but will not be applicable until June 15, 2021.
- **Medicare and Medicaid programs –** A final rule issued by HHS due to go into effect on March 22, 2021, revising regulations for the Medicare Advantage (Part C) program, Medicare Prescription Drug Benefit (Part D) program, Medicaid program, Medicare Cost Plan program and Programs of All-Inclusive Care for the Elderly (PACE).
- **Direct enrollment option –** A final rule issued by CMS due to go into effect on March 15, 2021, creating a direct enrollment option for insurers rather than being required to go through the federal Obamacare Exchange, HealthCare.gov.

Regulations Concerning Civil Rights and Civil Enforcement

- **Protections for infants born alive –** A proposed rule issued by HHS Office of Civil Rights (OCR) and CMS on January 15, 2021, clarifying that protections under Section 504 of the Rehabilitation Act, the Emergency Medical Treatment and Labor Act (EMTALA) and CMS hospital facility regulations apply to infants born alive, and that Section 504 precludes the denial of care to newborn infants with disabilities whose parents or guardians consent to treatment. This regulation is intended to protect premature infants, including those who survive botched abortions.
- **HHS regulatory procedure** – A final rule issued by HHS due to go into effect on March 22, 2021, requiring HHS to set expiration dates for its regulations, subject to exceptions.
- **Consent requirements for research on fetal tissue** – A notice of proposed rulemaking issued by HHS with comments due by February 12, 2021, requiring researchers using fetal tissue from elected abortions to obtain the informed consent of the pregnant donor and that the consent to donate the tissue is separate from the consent for the abortion. The required consent includes confirmation that the donor was not paid to donate the fetal tissue.
- **HIPAA amendments to improve coordinated care** – A notice of proposed rulemaking issued by HHS OCR, published on January 21, 2021, with comments due by March 22, 2021, to amend part of HIPAA to ease barriers in sharing patients' health information in order to facilitate coordinated care and case management. Under this proposed rulemaking, patients would have access to their own records and more transparency as to their rights to request records.

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