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Regulatory Implications of the 2021 Presidential Transition

On January 20, 2021, the Biden Administration will begin, which along with control of both congressional chambers by the Democratic Party in the 117th Congress, creates the opportunity for changes to certain regulatory actions taken at the end of the Trump Administration.

First, the Congressional Review Act (CRA) establishes a process through which Congress can disapprove a final rule promulgated by a federal agency if the rule was published in the Federal Register (FR) within a "lookback" period of 60 legislative days. Based on the 2020 congressional calendar, any final rule published in the FR on or after August 21, 2020 is subject to potential disapproval under the CRA. In order to overturn a final rule using CRA authority, a "joint resolution of disapproval" must be passed through Congress under an expedited process. Joint resolutions of disapproval can be passed with a simple majority in the Senate and are not subject to the filibuster.

Second, it is longstanding practice for incoming administrations to issue a memorandum to federal agencies to take certain actions on federal regulations that have not yet taken effect, in order to address last minute ("midnight") rulemaking by the previous administration. Actions typically called for in these memos include: 1) pausing any ongoing regulatory processes until a review has occurred; 2) immediately withdrawing any regulations sent to the FR but not yet published; and 3) temporarily postponing the effective date by 60 days of any regulations published in the FR but that have not yet taken effect in order to consider possible withdrawal or revision to these regulations. While it is not a requirement for incoming administrations to issue such a memorandum, recent reporting suggests that the Biden Administration intends to continue this practice.

Below is a list of regulations of interest to AMCP subject to CRA disapproval and/or delayed implementation.

Medicare Part D Rebate Rule

- Eliminates the Anti-Kickback Statute safe harbor protections for drug manufacturer price concessions to plan sponsors or contracted pharmacy benefit managers (PBMs).
- Establishes two new safe harbor protections for:
  - Manufacturer rebates that are reflected at the point of sale
  - Fair market value PBM service fees paid by manufacturers
- The final rule was published in the FR on November 20, 2020.
  - Effective date for elimination of the rebate safe harbor: January 1, 2022.
  - Effective date for the two new safe harbors: January 29, 2021.
- **Rule subject to: CRA disapproval and delayed effective date.**

Most Favored Nation (MFN) Model Interim Final Rule

- Creates a mandatory nationwide Medicare demonstration model that calculates the payment rate for certain prescription drugs based on the lowest per capita, GDP-adjusted price paid based on an index of OECD countries.

- Initially, the model will include the 50 medications that account for the largest percentage of Part B spending, with limited exceptions for certain drug categories.
    - Additional drugs will be included in the model as they enter the top 50 list by spending.
- The MFN Model was published in the FR on November 20, 2020 and scheduled to begin on January 1, 2021.
    - A court in California issued a preliminary injunction on implementation of the model in response to a lawsuit brought by pharmaceutical manufacturers on the grounds that CMS violated the Administrative Procedures Act in issuing the model as an interim final rule and not proceeding through notice and comment rulemaking.
- **Rule subject to: CRA disapproval**

Prescription Drug Importation Final Rule

- Allows for state- or tribal government-led programs, authorized by the FDA, for the importation of certain drugs, chosen by the program sponsor, from Canada.
- The final rule was published in the FR on October 1, 2020 with an effective date of November 30, 2020.
- **Rule subject to: CRA disapproval**

Medicare Coverage of Innovative Technologies (MCIT) Final Rule

- Establishes a national coverage pathway for new, innovative medical devices approved by the Food and Drug Administration (FDA) to allow Medicare beneficiaries faster access to these breakthrough technologies.
- The MCIT pathway will apply to devices that receive market authorization by the FDA through the agency's Breakthrough Devices Program, which has been used for market authorization of digital therapeutics.
- The MCIT final rule was published in the FR on January 14, 2021 with an effective date of March 15, 2021.
- **Rule subject to: CRA disapproval and delayed effective date**

Medicaid Best Price and Value-Based Purchasing (VBP) Final Rule

- Amends the calculation of best price under the Medicaid Drug Rebate Program (MDRP) detailing how manufacturers should account for VBP programs and contracts in their reporting of best price.
    - The rule modifies the MDRP regulation to permit the availability of a set of prices in a pricing structure that is part of a VBP arrangement to count as the statutorily required "lowest price available" for a drug.
- Additionally, the rule clarifies how the use of copay accumulator programs should be accounted for in the reporting of best price.
    - The final rule revises the MDRP regulation "to provide expressly that the exclusions [from best price] apply only to the extent the manufacturer ensures the full value of the assistance or benefit is passed on to the consumer or patient."
- The Medicaid Best Price and VBP Final Rule was published in the FR on December 31, 2020 with an effective date of March 1, 2021.
- **Rule subject to: CRA disapproval and delayed effective date**

Transparency in Coverage Final Rule

- The final rules set forth requirements for health plans in the individual and group markets to disclose cost-sharing information upon request to an enrollee, including an estimate of the individual's cost-sharing liability for covered items or services furnished by a particular provider.
- Under the final rule, plans are required to make this information available on an internet website and, if requested, in paper form, allowing enrollees to obtain an estimate of their out-of-pocket expenses and effectively shop for items and services.
- The Transparency in Coverage final rule was published in the FR on November 12, 2020 with an effective date of January 11, 2021.
- **Rule subject to: CRA disapproval**

Secure Electronic Prior Authorization for Medicare Part D

- Requires Part D plans to adopt the National Council for Prescription Drug Programs (NCPDP) SCRIPT standard version 2017071 electronic prior authorization standard.
- The Secure Electronic Prior Authorization for Medicare Part D final rule was published in the FR on December 31, 2020 with an effective date of February 1, 2021.
- **Rule subject to: CRA disapproval and delayed effective date**