



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 423

[CMS-4189-F2]

RIN 0938-AT94

Medicare Program; Secure Electronic Prior Authorization For Medicare Part D Program; Delay in Effective Date

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Final rule; delay in effective date.

SUMMARY: In accordance with the memorandum of January 20, 2021 from the Assistant to the President and the Chief of Staff, entitled “Regulatory Review,” this action temporarily delays for 60 days the effective date of the December 31, 2020 final rule entitled, “Medicare Program; Secure Electronic Prior Authorization For Medicare Part D”, which published on December 31, 2020.

DATES: The effective date of the final rule amending 42 CFR part 423 published at 85 FR 86824 on December 31, 2020, is delayed from February 1, 2021, to March 30, 2021.

FOR FURTHER INFORMATION CONTACT: Joella Roland, (410) 786-7638.

SUPPLEMENTARY INFORMATION:

Background and Provisions of the Final Rule

The January 20, 2021 memorandum from the Assistant to the President and Chief of Staff, entitled “Regulatory Freeze Pending Review,” instructed Federal agencies to delay the effective date of rules published in the **Federal Register**, but which have not yet taken effect, for a period of 60 days from the date of the memorandum.

The purpose of the final rule is to adopt a new standard for certain transactions

concerning Part D-covered drugs prescribed to Part D-eligible individuals under the Part D e-prescribing program. Under this final rule, Part D plan sponsors will be required to support version 2017071 of the National Council for Prescription Drug Programs (NCPDP) SCRIPT standard for four electronic Prior Authorization (ePA) transactions, and prescribers will be required to use that standard when performing ePA transactions for Part D-covered drugs they wish to prescribe to Part D-eligible individuals. Part D plans, as defined in 42 CFR 423.4, include Prescription Drug Plans (PDPs) and Medicare Advantage Prescription Drug Plans (MA-PDs); Part D sponsor, as defined in 42 CFR 423.4, means the entity sponsoring a Part D plan, MA organization offering a MA-PD plan, a Programs of All-Inclusive Care for the Elderly (PACE) organization sponsoring a PACE plan offering qualified prescription drug coverage, and a cost plan offering qualified prescription drug coverage. The ePA transaction standard will provide for the electronic transmission of information between the prescribing health care professional and Part D plan sponsor to inform the sponsor's determination as to whether or not a prior authorization (PA) should be granted. The NCPDP SCRIPT standard version 2017071 was adopted as a Part D e-prescribing program standard for certain defined transactions in the April 16, 2018 final rule (83 FR 16440) titled Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program that became effective June 15, 2018.

The effective date of that rule, which would have been February 1, 2021, is now effective on March 30, 2021.

The temporary delay in the effective date of this final rule is necessary to give Department officials the opportunity for further review and consideration of new regulations, consistent with the memorandum of January 20, 2021, from the Assistant to the President and Chief of Staff, entitled "Regulatory Freeze Pending Review."

Norris Cochran,

Acting Secretary.

Department of Health and Human Services.

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