



CENTER FOR MEDICARE

DATE: August 22, 2019

TO: All Prescription Drug Plans, Medicare Advantage- Prescription Drug Plans, Section 1876 Cost Plans, Medicare-Medicaid Plans, and PACE plans

FROM: Amy Larrick Chavez-Valdez, Director Medicare Drug Benefit and C & D Data Group

SUBJECT: Negative Change Requests (NCRs) no longer needed for §423.120(b)(5)(iv) Immediate Brand-Generic Substitutions

In the CY 2019 Formulary Information memorandum issued in Health Plan Management System (HPMS) on December 17, 2018, CMS requested that Part D sponsors that met the requirements of §423.120(b)(5)(iv) to make immediate generic substitutions provide required notice to CMS of any specific substitutions by submitting a negative formulary change request (NCR) via HPMS. Part D sponsors may provide this notice before or after making an immediate generic substitution. In an effort to improve efficiency and decrease burden on Part D plan sponsors, beginning with the CY2019 September monthly update window, Part D sponsors will no longer submit an NCR to CMS for immediate substitutions made consistent with §423.120(b)(5)(iv). Rather, Part D sponsors provide CMS required notice of specific generic substitutions by submitting monthly formulary update files that reflect the generic addition and corresponding change to the brand name drug.

Plan sponsors are reminded that brand-generic substitutions that do not meet all of the requirements of §423.120(b)(5)(iv) require 30 days' notice to CMS and an approved NCR prior to formulary update submissions. Additionally, §423.120(b)(5)(iv) requires Part D sponsors to also provide direct notice to affected beneficiaries of any specific generic substitutions that are made. For more information on notice and other requirements, see the April 16, 2018 final rule (83 FR 16440, 16604).

For additional questions, please email PartDFormularies@cms.hhs.gov.