DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, Maryland 21244-1850

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES
CENTER FOR MEDICAID & CHIP SERVICES

September 25, 2020

MEDICAID DRUG REBATE PROGRAM NOTICE **Release No. 187**

For
State Medicaid Programs

CMS Guidance to the States on the FDA Final Regulation "Importation of Prescription Drugs" Related to Section 804 of the Federal Food, Drug, and Cosmetic Act (FFDCA) and the Medicaid Drug Rebate Program

The Food and Drug Administration (FDA) published a Final Rule (#2020-199) that implements section 804(b) through (h) of the Federal Food, Drug, and Cosmetic Act (FFDCA) to allow importation of certain "eligible prescription drugs" shipped from Canada into the United States. The purpose of the final rule is to lower prescription drug costs for American consumers, while ensuring that importation poses no additional risk to public health and safety. This final rule permits states, the District of Columbia, territories, and Indian Tribes, and possibly at a future date, pharmacists and wholesalers, to submit time-limited Section 804 Importation Program (SIP) proposals to FDA for review and authorization.

Implementation

Under this final rule, section 804 of the FFDCA will be implemented through time-limited SIPs, which would be authorized by FDA and managed by states, the District of Columbia, territories, or Indian Tribes or in certain circumstances by pharmacists or wholesale distributors (SIP Sponsors). A SIP can also be co-sponsored by these same SIP sponsors. A SIP sponsor must specify the eligible prescription drugs that would be included in the SIP.

Importation Requirements

Section 804(c) of the FFDCA requires that each prescription drug imported under the regulations complies with section 505 (including with respect to being safe and effective for the intended use of the prescription drug). The final regulation (at 21 CFR 251.2) defines "eligible prescription drug" in relevant part, as a drug that meets the conditions in an FDA-approved new drug application (NDA) or abbreviated new drug application (ANDA) for a drug that is currently commercially marketed in the United States. Biological products licensed by the FDA are not considered to be eligible prescription drugs under this program.

Implications for Medicaid Drug Rebate Program (MDRP)

Based upon the final regulation, CMS has concluded that a drug imported under the Final Rule related to section 804 of the FFDCA would not meet the definition of a covered outpatient drug at section 1927(k)(2) of the Social Security Act (the Act). Section 1927(k)(2)(A) described a covered outpatient drug in part to mean, a drug, which is approved for safety under section 505 of the FFDCA, which includes approval under an NDA or ANDA. In contrast, as noted above,

eligible prescription drugs imported under this final rule are defined to "meet the conditions" of an FDA-approved NDA or ANDA for a drug that is currently commercially marketed in the United States. FDA further indicates that for drugs that are imported under this program, there will not be approval of an application under Section 505, and that they will not be subject to an NDA or ANDA approval. For these reasons, these imported drugs (SIP drugs) do not meet the definition of a covered outpatient drug as it is defined under section 1927 of the Act. Accordingly, because these prescription drugs would not fall under the definition of covered outpatient drugs for purposes of the MDRP, they would not be eligible for federal rebates under Section 1927 and manufacturers would not report these drugs for "best price" or Average Manufacturer Price purposes. Since these drugs are not considered covered outpatient drugs, CMS will not publish a National Average Drug Acquisition Cost (NADAC) for these drugs.

However, such drugs may be eligible for Medicaid federal financial participation (FFP) as prescribed drugs. See section 1905(a)(12) of the Act, and 42 CFR 440.20. To receive FFP for these imported drugs, states will be required to assure that their state plan permits coverage of prescribed drugs that are not covered outpatient drugs, and specify a reimbursement methodology for such drugs. The reimbursement methodology may be the state's existing approved ingredient cost and professional dispensing fee for covered outpatient drugs if it includes language for prescribed drugs. If the state's approved methodology does not include reimbursement for prescribed drugs, the state must submit a state plan amendment (SPA) to indicate the methodology for reimbursement for the ingredient cost and payment for the dispensing fee for these prescribed drugs.

If you have any further questions regarding reimported drugs as it relates to the MDRP please contact us at rxdrugpolicy@cms.hhs.gov.

Sincerely,

/s/

Melissa Harris, Acting Director
Disabled and Elderly Health Programs Group