[Date]

[Prescriber Name]  
[Address]  
[City, State ZIP]

Dear [Prescriber Name]:

You are receiving this letter because your patients will experience changes to their pharmacy benefits. Starting **«EFFECTIVE\_DT»**, these patients may not be able to fill their current medication at the pharmacy, based on the plan’s coverage changes.

**Background**

Under the Federal Food, Drug, and Cosmetic Act (FFDCA), certain drugs may be legally marketed despite lacking approval from the U.S. Food and Drug Administration (FDA) (e.g., drugs with grandfathered status). Historically, pharmacy benefit managers and others in the industry have been challenged with distinguishing these legally marketed drugs from other unapproved drugs. The FDA does not publicly identify which unapproved drugs are legally marketed, maintaining that it is the manufacturer’s responsibility to prove that a drug is legally marketed.

Universal exclusion of unapproved drugs is not clinically appropriate and may risk disrupting therapy for plan members using legally marketed drugs. Recently, the Centers for Medicare & Medicaid Services (CMS) began publishing a quarterly file of data[[1]](#footnote-1) provided by manufacturers of drugs covered by the Medicaid program.

Utilizing the information in the CMS data file, along with detailed clinical reviews, CVS Caremark® developed coverage recommendations for unapproved drugs. These coverage recommendations will help CVS Caremark clients appropriately manage utilization of unapproved drugs, while maintaining coverage for clinically appropriate, legally marketed[[2]](#footnote-2) drugs.

The enclosed chart lists the patients for whom you have recently written prescriptions that will no longer be covered on their drug benefit plan. Please consider a new or alternative drug therapy for your patients to avoid paying higher prescription costs.

Sincerely,

CVS Caremark

Enclosure

Dear [Prescriber Name]:

On behalf of [CLIENT NAME], below is a list of your patients who are taking an unapproved drug that will no longer be covered. Where possible, alternatives are listed for these unapproved products. If necessary, please reach out to your local pharmacist for additional suggestions of alternatives that are available in your area.

**To avoid disruptions in drug therapy, please consider an alternative medication when you process a refill request for these patients.**

**Patient Name Patient ID Date of Birth Drug Name Alternative Option(s)**

xxxxxxxxxxxxxx xxxxxxxxxxx xxxxxxxxxxx xxxxxxxxxxx xxxxxxxxxxxx

xxxxxxxxxxxxxx xxxxxxxxxxx xxxxxxxxxxx xxxxxxxxxxx xxxxxxxxxxxx

xxxxxxxxxxxxxx xxxxxxxxxxx xxxxxxxxxxx xxxxxxxxxxx xxxxxxxxxxxx

1. The data file contains information about unapproved drugs, including the legal authority under which the drug is marketed and the statutory basis for coverage under the Medicaid program. [↑](#footnote-ref-1)
2. As reported by the manufacturer to CMS and utilized in making a determination of coverage under the Medicaid program. [↑](#footnote-ref-2)