OCT 1 1 2019

Raymond R. Carlson, R.Ph.
Pharmacist/Owner
RC Outsourcing, LLC
102 East Water Street
Lowellville, OH 44436

Re: Docket No. FDA-2019-P-3311

Dear Mr. Carlson:

This letter responds to your citizen petition received on July 9, 2019 (Petition), concerning compliance with the Drug Use Review provision of the Omnibus Budget Reconciliation Act of 1990 (Public Law 101-508) (OBRA-90), which amended section 1927 of the Social Security Act (SSA). OBRA-90 requires states, as a condition of participation in the Medicaid program, to implement drug use review programs for covered outpatient prescription drugs in order to assure that such prescriptions are appropriate, are medically necessary, and are not likely to result in adverse medical results.[1] States must implement programs for prospective drug use review by providing for a review of drug therapy before prescriptions are dispensed, including screening for potential drug therapy problems.[2] States must also establish standards for patient counseling as part of a prospective drug use review program.[3] The statute also requires states to implement programs for retrospective drug use review through ongoing periodic examination of claims data and other records that may identify patterns of inappropriate conduct by physicians, pharmacists, and individuals or groups.[4] Drug use review programs must also assess data on drug use against predetermined standards.[5] Finally, drug use review programs must have an educational outreach component designed to educate practitioners on common drug therapy problems to improve prescribing and dispensing practices.[6]

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[1] 42 U.S.C. 1396r-8(g)

[2] 42 U.S.C. 1396r-8(g)(2)(A)(i)

[3] 42 U.S.C. 1396r-8(g)(2)(A)(ii)

[4] 42 U.S.C. 1396r-8(g)(2)(B)

[5] 42 U.S.C. 1396r-8(g)(2)(C)

[6] 42 U.S.C. 1396r-8(g)(2)(D)

In the Petition, you request that the Food and Drug Administration (FDA) "enforce or cause to enforce compliance with OBRA-90 within retail and mail order pharmacies if violations are found to be occurring" (Petition at 1). The Petition further asks FDA to "investigate compliance with Section G, entitled 'Drug Use Review' within the Omnibus Reconciliation Act of 1990 (OBRA-90) (H.R. 5835) (101st)" (Petition at 1). The federal agency tasked with implementing and enforcing section 1927 of the SSA (OBRA-90) and related regulations is not FDA, but rather Centers for Medicare and Medicaid Services (CMS) (formerly the Health Care Financing Administration) within the Department of Health and Human Services.[7] Section 702(a)(1)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 372(a)(1)(A)) gives FDA authority "to conduct examinations and investigations for the purposes of [the Federal Food, Drug, and Cosmetic Act] . . . ." This authority does not extend to the SSA.

Accordingly, because FDA is not the appropriate federal agency to take the action you have requested, your Petition is denied. We defer to CMS to interpret and enforce its regulations that implement the statutory language of OBRA-90. Additionally, per 21 CFR 10.30(k), the citizen petition procedures described in §10.30 do not apply to "referral of a matter to a United States attorney for the initiation of court enforcement action and related correspondence . . . ." Agency decisions to take, or refrain from taking, enforcement actions are decisions related to referral of a matter to a United States attorney for the initiation of court enforcement action for violations of the FD&C Act. Therefore, your request that the Agency enforce compliance with OBRA-90 is also denied because it is not properly the subject of a citizen petition under 21 CFR 10.30.

Sincerely,

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research

[7] Regulations implementing the Drug Use Review provision of OBRA-90 can be found at 42 CFR 456.703.