DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

MAR - 8 2018

Lee Ann C. Stember
President & CEO
National Council for Prescription Drug Programs
9240 E. Raintree Drive
Scottsdale, AZ 85260

Dear Ms. Stember:

Thank you for your letter requesting that the Centers for Medicare & Medicaid Services (CMS) reexamine the Medicare Part D and Medicaid provider enrollment requirements. We appreciate your comments and suggestions on these issues.

As you know, CMS regulations at 42 CFR § 423.120 require most prescribers to be enrolled in Medicare in an active status or to have validly opted out, in order for Medicare to pay for drugs these individuals prescribe to patients with Part D prescription drug benefit plans. While provider enrollment is the gateway to the Medicare program and is essential to safeguarding the Medicare Trust Funds from ineligible providers and suppliers, CMS continues to take into consideration the concerns from the provider community related to the current Part D enrollment requirement. In response to concerns raised by yourself and others, CMS is actively working towards a more targeted approach to reduce provider burden while continuing to protect the Trust Funds and Medicare beneficiaries. As such, CMS published CMS-4182-P[1] on November 16, 2017, which proposes to rescind the Part D enrollment requirement in 42 CFR § 423.120, effective January 1, 2019.

Instead, CMS proposes to create a Preclusion List that would consist of providers who are currently revoked from the Medicare program under § 424.535 and are under an active reenrollment bar, or have engaged in behavior for which CMS could have revoked the provider to the extent applicable if he or she had been enrolled in Medicare, and CMS determines that the underlying conduct that led, or would have led, to the revocation is detrimental to the best interests of the Medicare program. Under this proposal, CMS would make the Preclusion List available to the Part D sponsors. The Part D sponsors would be required to reject a pharmacy claim (or deny a beneficiary request for reimbursement) for a Part D drug that is prescribed by an individual on the Preclusion List.

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[1] RIN 0938-AT08 - 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

Regarding Medicaid provider enrollment requirements, CMS continuously works with states and other program stakeholders to implement the screening and enrollment requirements, including addressing state-specific issues that may require technical assistance. As part of CMS's efforts, in March 2016, CMS published the Medicaid Provider Enrollment Compendium (MPEC), which includes sub-regulatory guidance intended to assist states in their provider enrollment and screening implementation efforts. The MPEC clarifies the regulatory requirements, responds to frequently asked questions, establishes deadlines and milestones for implementation, and provides guidance for states to leverage Medicare screening activities to the greatest extent possible.

In January 2017, CMS released an updated MPEC that provided additional guidance about the Medicaid managed care screening and enrollment requirements. The Medicaid Managed Care Final Rule, which CMS published in the Federal Register on May 6, 2016 (81 FR 27497), requires states to screen and enroll network providers of Medicaid managed care plans, effective July 1, 2018. However, section 5005(b)(2) of the 21st Century Cures Act (Cures Act), enacted in December 2016, superseded this rulemaking and required earlier compliance with the Medicaid managed care screening and enrollment requirements, effective January 1, 2018.

In addition, section 1902(kk)(7) of the Social Security Act requires State Medicaid Agencies (SMAs) to enroll as participating providers all ordering, referring, or prescribing physicians or other professionals providing services under the state plan or under a waiver of the plan. This statutory requirement, in part, helps make sure that Medicaid pays only for prescriptions written by qualified Medicaid prescribers. This requirement also supports CMS's responsibility to protect Medicaid patients and the integrity of the program, while minimizing disruption to patients' access to needed medications and the administrative burden on the provider community. To date, 31 SMAs have already implemented the ordering, referring, and prescribing requirements, and the few remaining states continue to make progress.

In instances where extraordinary circumstances such as a natural disaster prevent enrollment, CMS has exercised its authority to waive provider enrollment requirements to reduce access to care issues for impacted beneficiaries. Most recently, CMS issued provider enrollment waivers for areas impacted by Hurricanes Harvey and Irma, as well as the California wildfires. These waivers allowed patients in affected counties to receive services and necessary medical supplies and prescriptions from providers in other counties or out-of-state providers who met minimal requirements in both the Medicare and Medicaid programs.

Thank you for your continued collaboration as we work to reduce fraud, waste, and abuse throughout the Medicare and Medicaid programs, while protecting beneficiaries and reducing provider burden.

Sincerely,

Seema Verma