

January 16, 2018

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4182-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Ms. Verma,

The Compliance Team, Inc. (TCT) is a Pennsylvania-based national healthcare accreditation organization with authority granted by the Secretary of Health and Human Services to accredit Medicare Part A- Rural Health Clinic (RHC), and Patient-Centered Medical Home (PCMH) practices as well as Part B- Durable Medical Equipment, Prosthetics, Orthotics, Supplies (DMEPOS) providers.

The Compliance Team, which is a WBENC certified woman-owned and nurse directed organization, was formed in 1994. The first of our “operations-based” Exemplary Provider® accreditation programs were launched in 1998. Formal managed care recognition soon followed starting in 1999 with recognition from North Carolina BC/BS of TCT’s accreditation process for DMEPOS providers.

Included in the number and types of healthcare organizations accredited by TCT over the ensuing years are thousands of community pharmacies located in all fifty states, Puerto Rico, the US Virgin Islands as well as throughout rural America.

The Compliance Team’s suite of Pharmacy Services accreditation tracks has grown over the years to include programs for Sterile and Non-sterile Compounding, Infusion, Long-term Care, Mail Order, Specialty Drug, Retail Clinic, DMEPOS, Remote Rx/ Tele-Pharmacy and Patient-Centered Pharmacy Home™ (PCPH) accreditation for advanced pharmacy services.

It is important to note that TCT’s Safety-Honesty-Caring® accreditation quality standards and evidence of compliance for Specialty Drug pharmacy were first developed in the year 2000, and when applicable have been actively employed as part of our core pharmacy accreditation process since that time.

Given our extensive experience accrediting Specialty Drug pharmacy services, we greatly appreciate the opportunity to provide comments on ways in which Medicare beneficiaries could maximize their access to their preferred pharmacies for getting the specialty drugs that have been prescribed for them. In addition to increasing beneficiary access to their preferred specialty drug community pharmacy, we are also confident that the recommendations that follow will ultimately lead to more affordable Part D plan pharmacy accreditation choices.

"Any Willing Pharmacy" Provisions

Congress established "any willing pharmacy" provisions to apply to pharmacies participating in the Medicare Part D program. 42 U.S.C. § 1395w-104(b)(1)(A). Regulations established by the Centers for Medicare and Medicaid Services (CMS) require Medicare Part D plan sponsors "to agree to have a standard contract with reasonable and relevant terms and conditions of participation whereby any willing pharmacy may access the standard contract and participate as a network pharmacy." 42 C.F.R. 423.505(b)(1) and (18).

The intended result of the "any willing pharmacy" provision is to ensure that any pharmacy wishing to participate in a network may do so. CMS highlighted this fact in the preamble to the Medicare Prescription Drug Benefit Final Rule issued on January 28, 2005:

Given the current industry practice of broad pharmacy networks and given Medicare Part D's any willing pharmacy provision, which includes the requirement that plans offer reasonable and relevant standard terms and conditions for network participation to all similarly situated pharmacies, we anticipate that all pharmacies that wish to participate in Medicare Part D will be able to do so.¹

The Problem

Many pharmacies have been a victim of arbitrary and baseless exclusion from participation in Part D networks. The pharmacy benefit managers ("PBM's") that manage these Part D networks are requiring terms and conditions for participation that are not reasonable and relevant. These actions are to the detriment of the numerous Medicare beneficiaries that are no longer able to use their local, chosen pharmacy, often with little or no notice, and threaten the very survival of the long-standing pharmacies involved.

A prime example involves the unjustified PBM contract condition that restricts specialty drug network pharmacies to the PBM's choice of just 1 accreditation vendor. Raising concerns even more is the fact that this accreditation vendor heretofore had no prior experience in provider-based healthcare accreditation, and their fees commonly run 5x's more than the customary charges for the same service performed by The Compliance Team, Inc. or other like competitors.

Such monopolistic behavior dramatically increases costs to independent pharmacies and creates limited pharmacy access for beneficiaries. To make matters worse for prospective specialty drug network pharmacies, some PBMs are now requiring a second seemingly redundant and unnecessary accreditation. It is important to point out that CMS does not have a core accreditation requirement for any area of pharmacy services.

By restricting specialty drug pharmacy accreditation to choice of just one or two exorbitantly expensive sources is neither reasonable, nor relevant. It is readily apparent that these now common PBM practices operate as a barrier to network participation for many smaller, independent, often rural and otherwise "willing" pharmacies.

Adding to the need to reign-in these anti-competitive practices, The Compliance Team has experienced first hand that the nation's major PBMs lack a formal good faith vetting process for adding qualified accreditation vendor choices. Despite numerous formal requests over the past few years, the nation's three primary PBMs cannot or will not disclose to us their core criteria regarding their specialty drug pharmacy accreditation vendor vetting.

Over the years, The Compliance Team, Inc. and its Exemplary Provider® accreditation process has undergone multiple successful vetting processes by the Centers for Medicare and Medicaid Services as well as a whole host of national and regional managed care and state entities. Yet, despite our most earnest attempts to seek similar recognition from the nation's major PBMs, The Compliance Team has been rebuffed each time; often in a most unprofessional and insulting manner.

Recommendations

Given the overwhelming evidence that PBMs are assuming unwarranted monopolistic powers when it comes to specialty drug pharmacy accreditation vendor options, it is The Compliance Team's recommendation that CMS reign-in such overreach by requiring that PBMs open their network accreditation choices to established national pharmacy accreditation organizations such as The Compliance Team, Inc., and/or set in place PBM accreditation vetting procedures that follow federally approved guidelines.

Such actions will undoubtedly result in allowing many more "willing pharmacies" into the nation's specialty drug PBM networks; thus expanding stronger beneficiary access and lowering overall plan costs as a result.

Proposed Amendment to 42 C.F.R. § 423.505 (Part D Contract Provisions)

The Part D plan sponsor agrees to -

Recognize any accreditation organization (1) approved by CMS to accredit provider-based services with (2) demonstrated pharmacy standards and experience. Demonstrated pharmacy experience shall include the following programs:

- Community Pharmacy Accreditation (Including Mail Order)
- Non-Sterile Compounding Accreditation (Referenced by USP 795 or current version)
- Sterile Compounding Accreditation (Referenced by USP 797 or current version)
- Specialty Drug Accreditation
- Infusion Therapy Accreditation
- Long-Term Care Accreditation

Demonstrated pharmacy standards shall include the following:

- Corporate Compliance Plan Including OIG and SAM Exclusion Verifications
- Standards of Conduct with Non-retaliation statement
- Confidentiality Statement
- Scope of Services
- Billing Practices
- Financial Management
- Human Resources (Includes License Verification, Independent Contractors, and Training)
- Quality Improvement Program (Includes Patient Satisfaction and Complaints)
- Risk Management (Includes Patient and Employee Incidents/adverse events)
- Infection Control
- Equipment Management
- Patient Service and Instruction
 - Immunization Services
 - Medication Therapy Management
 - Health Screening Tests/Medication Reconciliation/Care Transition Services
- Pharmaceutical Management
 - Non-Sterile/Sterile Compounding
 - Specialty Pharmacy
 - Infusion Therapy Pharmacy
 - Long-Term Care Pharmacy
- Government Regulatory

On behalf of all our pharmacy clients, The Compliance Team appreciates the opportunity to provide comment to CMS about this important issue.

Regards,



Steve Simmerman
Executive Vice-President

1. Medicare Prescription Drug Benefit Final Rule, 70 Fed. Reg. 4194, 4506 (Jan. 28, 2005).