



American Pharmacists Association[®]
Improving medication use. Advancing patient care.

April 25, 2016

Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services, Room 445-G
Attention: CMS-6058-P
P.O. Box 8013
Baltimore, MD 21244-8013

[Submitted electronically to www.regulations.gov]

Re: Medicare, Medicaid, and Children’s Health Insurance Programs; Program Integrity Enhancements to the Provider Enrollment Process; Proposed Rule

Dear Acting Administrator Slavitt,

APhA is pleased to submit these comments on the Centers for Medicare & Medicaid Service’s proposed rule regarding Medicare, Medicaid, and Children’s Health Insurance Programs; Program Integrity Enhancements to the Provider Enrollment Process (the “Proposed Rule”). Founded in 1852 as the American Pharmaceutical Association, APhA represents more than 62,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, hospitals, long-term care facilities, community health centers, managed care organizations, hospice settings, and the uniformed services.

APhA appreciates CMS’s goal in the Proposed Rule to address various integrity issues and vulnerabilities in the Medicare, Medicaid and CHIP programs. While APhA supports efforts to minimize waste and maximize the beneficial impact federal health care resources can have on patients, some of the efforts identified in the Proposed Rule may unnecessarily impact patients negatively.

I. §425.505 Basic Enrollment Requirement

The Proposed Rule states “that to order, certify, refer or prescribe any Part A or B service, item or drug, a physician or, when permitted, an eligible professional must be enrolled in Medicare in an approved status or have validly opted-out of the Medicare program.” APhA has concerns that this requirement may unintentionally exclude pharmacists, who CMS has confirmed are not able to enroll in Medicare. While APhA is aware that pharmacists are not able to receive direct payment under Medicare Part B for many pharmacists’ services, pharmacists do

participate in various services that are covered by Medicare Parts A and B. APhA believes the language in the Proposed Rule could be interpreted broadly to prohibit pharmacists' involvement in team-based care and provision of coordinated and comprehensive care, which is counter to many of the policies for which the Department of Health and Human Services and CMS has advocated (e.g. accountable care organizations, medical homes, incident-to-physician services). Therefore, APhA encourages CMS to clarify, much like it did for a similar Part D requirement, that the Proposed Rule will not prevent pharmacists from engaging in services currently covered by Medicare because they are ineligible to enroll in Medicare.

In 2015, APhA worked with CMS to resolve a problem that resulted from a similar provision in the Medicare Advantage and Prescription Drug Benefit Programs for Contract Year 2015 Final Rule, which required prescribers to be enrolled in, or validly opted out of, Medicare for their prescriptions to be covered under Part D. When CMS became aware that certain pharmacists were allowed to prescribe under state authority but could not enroll in or opt of Medicare, it issued an Interim Final Rule¹ (IFR) to correct this inadvertent exclusion and mitigate potential interruptions to beneficiaries' access to needed medications. The IFR confirmed that prescriptions by pharmacists who are permitted to prescribe by state or other applicable law would be covered by Part D. Therefore, we ask that CMS include similar language in this regulation to clarify that the Proposed Rule does not restrict Medicare Part A and B beneficiary access to pharmacists, an accessible and qualified health care professional. Accordingly, APhA assumes, in addition to pharmacies enrolled as mass immunizers and suppliers of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS), pharmacists involved in providing Medicare-covered services and/ or Medicare Part D prescriptions will be covered by the provisions of the Proposed Rule.

II. Disclosable event Penalties

Under the Proposed Rule, failing to include a disclosable event in an initial or revalidating application could lead to health care professionals being denied participation in Medicare and other federal programs. APhA is concerned that providers will be unable to comply with the requirement related to disclosure because not only is it difficult to determine whether a disclosable event requirement is triggered,² the Proposed Rule's definition of affiliation³ is ambiguous, and can be interpreted broadly. APhA also believes that the Proposed Rule may discourage co-ownership arrangements between health care entities and providers, which may negatively impact team-based delivery of care. While it is important for business owners and other affiliates to be engaged in their company's operations, APhA recommends that CMS takes into account the type or degree of affiliation, level of risk to the Medicare Program

¹ See 80 FR 25958 (May 6, 2015) (interim final rule)

² See §424.519 details the circumstances that would rise to the level of a "disclosable event".

³ See §424.502 Affiliation means, for purposes of applying §424.519, any of the following:

- (1) A 5 percent or greater direct or indirect ownership interest that an individual or entity has in another organization.
- (2) A general or limited partnership interest (regardless of percentage) that an individual or entity has in another organization.
- (3) An interest in which an individual or entity exercises operational or managerial control over or directly or indirectly conducts the day-to-day operation of another organization (including, for purposes of this provision, sole proprietorships), either under contract or through some other arrangement, regardless of whether or not the managing individual or entity in a W-2 employee of the organization.
- (4) An interest in which an individual is acting as an officer or director of a corporation.
- (5) Any reassignment relationship under §424.80.

and “knew or should reasonably have known” standard when determining compliance and assessing penalties.

III. Due process

We commend CMS for pursuing efforts to limit fraud, waste and abuse, however, we believe that such efforts must be accompanied by appropriate due process. Given the risk of unnecessary denials or revocations and the likely appeals that will follow, APhA encourages CMS to enhance efforts to ensure that health care professionals who have had their Medicare enrollment revoked or denied have the opportunity to discuss their matter with CMS. In addition, CMS should also clarify how it will treat health care professionals whose Medicare payments were improperly suspended because they did not actually commit fraud.

We appreciate CMS’s continued work to strengthen and improve Medicare, Medicaid, CHIP and our health care system as a whole. As CMS moves forward, we hope you will use APhA as a resource. Thank you again for the opportunity to provide information on this important issue. If you have any questions or require additional information, please contact Jenna Ventresca, JD, Associate Director of Health Policy, at jventresca@aphanet.org or by phone at (202) 429-7538.

Sincerely,



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Executive Vice President and CEO

cc: Stacie S. Maass, RPh, JD, Senior Vice President, Pharmacy Practice and Government Affairs