



JUL 20 2016

Administrator

Washington, DC 20201

Robert L. Wergin, MD
American Academy of Family Physicians
1133 Connecticut Ave, NW
Suite 1100
Washington, DC 20036

Dear Dr. Wergin:

Thank you for your letter about diabetes testing supplies (DTS) for people with Medicare. We agree with you that diabetes is one of the costliest and deadliest of all chronic diseases. Your letter raises a few concerns on DTS.

The Centers for Medicare & Medicaid Services (CMS) is tasked with maintaining the delicate balance between protecting the Medicare Trust Fund from abuse or fraud, while also ensuring access to quality care for Medicare beneficiaries and minimizing provider burden. CMS and the Department of Health and Human Services (HHS), Office of Inspector General's (OIG's) investigations and prior studies have found that diabetes test strips is an area vulnerable to fraud, waste, and abuse.¹ Accordingly, CMS has created DTS documentation requirements that include documentation requirements for diabetes test strips commensurate with the risks inherent in this benefit. Specifically if the physician is prescribing DTS in quantities above the maximum monthly allowances, CMS requires additional supporting documentation for Medicare coverage.

In your letter, you suggest that "[i]deally, it should be acceptable for a physician to write for 'diabetic supplies' which would encompass syringes, needles, test strips, lancets, glucose testing machine, etc., with only a need to provide a diagnosis and an indication such a prescription is good for the patient's lifetime." We note that coverage of DTS under the Medicare Part B durable medical equipment (DME) benefit is limited to those DME supplies that are reasonable and medically necessary. While Medicare Part B includes coverage for DME such as blood glucose monitors and blood-testing strips, supplies that are not medically necessary for the effective use of a blood glucose monitor, such as syringes and needles, are not covered under the Medicare Part B DME benefit. Additionally, CMS believes that itemized information is necessary to support claims payment. However, CMS is always interested in reducing any burden on providers and would like to meet with you to discuss ways to minimize documentation requirements while maintaining the integrity of the Medicare Trust Fund. Please contact Melanie Combs-Dyer, Director of CMS's Provider Compliance Group, to set up a phone or in-person meeting. Melanie can be reached at 410-786-7683 or melanie.combs-dyer@cms.hhs.gov.

¹<http://oig.hhs.gov/oei/reports/oei-04-11-00330.pdf>

In regards to your request to have HHS stop DME suppliers from contacting beneficiaries when it is not solicited, CMS asks for more information on this matter so that appropriate action can be taken.

Section 1834(a)(17)(A) of the Social Security Act (the Act) prohibits suppliers of DME from making unsolicited telephone calls to Medicare beneficiaries regarding the furnishing of a covered item, except in three specific situations: (i) the beneficiary has given written permission to the supplier to make contact by telephone regarding the furnishing of the covered item; (ii) the supplier has furnished a covered item to the beneficiary and the supplier is contacting the individual only regarding the furnishing of such covered item; or (iii) if the contact is regarding the furnishing of a covered item other than a covered item already furnished to the individual, the supplier has furnished at least one covered item to the beneficiary during the 15-month period preceding the date on which the supplier makes such contact.

Under Section 1834(a)(17)(B) of the Act, if a supplier knowingly contacts a beneficiary in violation of Section 1834(a)(17)(A) of the Act, no payment may be made under Part B for any item subsequently furnished to the beneficiary by the supplier. Accordingly, such claims for payment are false and violators are potentially subject to criminal, civil, and administrative penalties, including exclusion from Federal health care programs.² In order to address these incidents, please either provide the information on the DME suppliers making the unsolicited telephone calls back to me in writing or contact 1-800 MEDICARE and report all occurrences so that CMS and/or HHS OIG can investigate and take appropriate action.

Finally, regarding your concern about the efficacy of “unbranded” DTS, Medicare coverage and payment is not allowed for DTS or other products that do not meet safety and efficacy requirements established by the Food and Drug Administration (FDA). Under Medicare, suppliers of DME must be accredited and meet quality standards, including the requirement to only furnish products that meet applicable FDA regulations and medical device effectiveness and safety standards. Nonetheless, we suggest that you provide detailed information about your concerns with specific products directly to the FDA for their consideration. In addition, we are not certain what “unbranded” diabetes test strips refers to, as generic test strip products were taken off the market in the early 1990s. With regard to brands of test strips furnished via mail-order to Medicare beneficiaries, the HHS OIG analyzed supplier documentation of brands of test strips furnished to beneficiaries for the 3-month period of April to June 2013 leading up to implementation of the national mail-order program for diabetes test strips on July 1, 2013.³ They also analyzed supplier documentation for the brands of test strips furnished to beneficiaries for the 3-month period from July through September 2013.⁴ These studies showed little change in the top 10 brands furnished to beneficiaries before and after implementation of the mail order program. We suggest that you provide detailed information about your concerns regarding the efficacy of specific DTS products directly to the FDA for their consideration.

² http://oig.hhs.gov/fraud/docs/alertsandbulletins/fraudalert_telemarketing.pdf

³ <http://oig.hhs.gov/oei/reports/oei-04-13-00681.pdf>

⁴ <http://oig.hhs.gov/oei/reports/oei-04-13-00680.pdf>

Page 3 – Robert L. Wergin, MD

Thank you, again, for your interest in this issue and your letter regarding the Medicare requirements for prescribing DTS. I look forward to working with you to ensure that beneficiaries receive appropriate and necessary DTS while also reducing the fraud, waste and abuse associated with this benefit.

Sincerely,

A handwritten signature in blue ink, appearing to read "Andrew Slavitt", with a stylized flourish at the end.

Andrew M. Slavitt
Acting Administrator