May 8, 2013

Marilyn Tavenner, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445–G, Hubert H. Humphrey Building
200 Independence Avenue SW.
Washington, DC 20201

Dear Administrator Tavenner:

I am writing on behalf of the American Academy of Family Physicians (AAFP), which represents 110,600 physicians and medical students nationwide, to seek relief from the burdensome and non-value-added Medicare requirements associated with the prescribing of diabetic supplies. We believe that there is an opportunity to simplify the current Medicare rules surrounding prescription of diabetic supplies in such a way that patients and physicians would benefit without compromising the integrity of the Medicare program. We seek the chance to collaborate with the agency in pursuing this goal.

Diabetes is one of the most common, costly, and deadliest of chronic illnesses, and patients with diabetes need diabetic testing supplies to adequately care for themselves. Difficulty in obtaining diabetic supplies can actually lead to poorer health outcomes for patients. Family physicians simply want to be able to efficiently and effectively prescribe what their diabetic patients need to help manage their condition in a way that maintains their health. Unfortunately, the current Medicare rules surrounding prescription of diabetic supplies impede this goal and add no discernible value to the care of such patients.

It is our understanding that the following documentation is currently required for Medicare glucose testing supplies:

1. Detailed written order, including
   a. Patient name;
   b. Detailed description of the items being provided, including:
      i. The specific frequency of testing ("as needed" or “PRN orders” are not acceptable), and
      ii. The length of need;
   c. Treating physician’s signature and date order signed; and
   d. Start date of the order (only required if the start date is different from the signature date).
2. Documentation that supports the patient meets all of the following five basic coverage criteria:
   a. The patient has a documented diagnosis of diabetes and is being treated by a physician for the condition.
   b. The glucose monitor, related accessories, and supplies are ordered by the physician responsible for the patient’s diabetes management. The physician maintains records that reflect the care and include the medical necessity for the prescribed frequency of testing.
   c. The patient or caregiver has successfully completed training or is scheduled to begin training in the use of the glucose monitor and supplies.
   d. The patient or caregiver is capable of using the test results to assure appropriate blood glucose control.
   e. The glucose monitor is designed for home use.

Further, if the physician is prescribing blood glucose testing supplies in quantities above the maximum monthly allowances, Medicare requires supporting documentation that meets criteria A-F, as follows:
   A. Coverage criteria 2.a-e (as noted above) are met.
   B. The supplier’s files contain a copy of the treating physician’s order.
   C. The patient has nearly exhausted the supply of test strips and lancets, or exhausted the useful life of one lens shield cartridge previously dispensed.
   D. The treating physician’s order for testing frequency exceeds utilization guidelines, and the medical record documentation supports the need for testing frequency above utilization guidelines (i.e. the physician has documented the specific reason for the higher testing frequency).
   E. The treating physician has seen the patient and evaluated his or her diabetes control within six months of the date of the order for the quantities of supplies exceeding utilization guidelines.
   F. The physician/supplier’s records contain a copy of the patient’s testing log or other physician records, such as a narrative statement, that adequately documents the patient’s testing frequency.

If the patient regularly uses quantities of supplies that exceed the utilization guidelines, new documentation to support these supply quantities must be obtained every six months.

We understand that glucose testing and other diabetic supplies are an identified area of claims processing errors within the Medicare program and that physicians have a role to play in fraud prevention. However, the related requirements have become overly burdensome with little to no value added to the actual care of the diabetic patient. For example:
   • A “detailed description of the items being provided” is being interpreted to mean that physicians must go so far as to specify the exact brand of machine, test strips, and lancets needed by the patient. Typically, the brand name of the product is immaterial, and it seems unreasonable to request this information from the physician.
The need to specify "length of need" also is questionable. Diabetes is a chronic disease with no known cure. Patients with diabetes need glucose testing supplies for as long as they are able to care for themselves in their own home. Asking physicians to specify length of need for such equipment and supplies puts them in an untenable position of predicting a future that is not knowable.

Ideally, 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. When treating diabetes, diabetic supplies are part of data gathering and medication delivery regardless of the brand. Clinical relevance is the medication and frequency of use/testing. As long as physicians are clear in describing the frequency, they should be able to write the generic terms for these items without having the hassle of knowing exactly which one is on the formulary of a particular health plan such as Medicare.

In practice, the documentation requirements are onerous to our members and consume valuable physician time that is not germane to the actual care of the patient. Clearly, the documentation requirements add administrative cost to both Medicare and the family physician and diminish the opportunity for better diabetic care. Family physicians' time is better spent helping patients manage their diabetes, not providing additional paperwork to justify what the patient needs for such a basic service in diabetes.

In recent years, CMS has shown a willingness to reconsider its current rules and to seek opportunities for simplification that benefit patients and providers without compromising the integrity of the Medicare program. We believe that there is an opportunity to do that with the rules surrounding prescription of diabetic supplies, and we expect that by streamlining this process, patients will have better outcomes at a lower cost to the program. We would welcome the chance to collaborate with you or your staff in exploring that possibility. If, like us, you are interested in doing so, please contact Mr. Robert Bennett, Federal Regulatory Manager, at 202-232-9033 or rbennett@aafp.org.

Thank you for your time and consideration of this matter.

Sincerely,

Glen Stream, MD, MBI, FAAFP
Board Chair

Cc: Amanda Burd (CMS)