



October 3, 2014

Marilyn Tavenner
Administrator
Center for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Room 310G, Mail Stop 314G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS Reimbursement for Continuous Glucose Monitoring Systems

Dear Administrator Tavenner:

I am writing about congressional legislation designed to require that CMS reimburse for Continuous Glucose Monitoring Systems (CGM). I am the President of a small medical device company that offers an FDA-cleared platform that provides Internet-based monitoring of blood glucose.

I believe that CMS should reimburse for CGM systems for certain patients whose condition would require constant monitoring. CGM systems represent outstanding technology that may provide clinical benefit to patients on insulin who regularly experience nocturnal hypoglycemia or hypoglycemic unawareness. For these patients, I believe, CGM systems may also provide cost savings to the healthcare system by preventing adverse events.

Since most Type 2 diabetes patients do not require insulin, the cost of CGM would not be justifiable. However, poor blood glucose control in these patients often leads to diabetes complications that are devastating to the individual and costly to the healthcare system. I believe Internet-based blood glucose monitoring may represent a cost-effective solution and would provide an effective tool for providers to remotely monitor patient blood glucose. For many patients in Medicare who do not require constant monitoring, I believe a sensible policy would be to reimburse first for Internet-based monitoring systems and then provide the CGM option for patients who fail on this less costly, Internet-based technology. Similar step-edit and prior authorization programs are widely used by payers

My company has conducted two clinical trials. The results of the first trial indicated that Internet-based monitoring of patient blood glucose was associated with an average A1c reduction of 1.2%, from 8.8% to 7.6% in an insulin-requiring population. In our second trial, we compared Internet-based blood glucose monitoring with a CGM system. Despite the significantly lower costs of the Internet-

based system, the two systems achieve statistically comparable results in lowering A1c. Our principal investigator for these trials would be happy to discuss these outcomes with your medical team.

More information about our clinical trials can be found on our website, here:
<http://www.alrt.com/hec/clinical-support>

I commend the congressional sponsors of H.R. 5644 and S. 2689 for their willingness to bring new technologies to our fellow citizens living with diabetes. I also believe that any reimbursement for CGM systems should be coupled with reimbursement for less expensive monitoring systems, such as my company's Health-e-Connect system. Payers, such as CMS, as well as providers, can then match the appropriate technology to the appropriate patient.

Thank you for your consideration and do not hesitate to have your staff contact me in the event that you have questions.

Sincerely,

A handwritten signature in black ink, appearing to read "William S. Smith". The signature is fluid and cursive, with a long horizontal stroke at the end.

William S. Smith
President
ALR Technologies, Inc.