



## Opportunity for Medicare to Reduce Millions in Costs

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At the same time that the federal government seeks to cut Medicare spending, awareness is growing about a fraudulent practice around diabetes test strips that is running up program costs and putting the health of patients at risk.

At the heart of the issue is the need for patients with diabetes to test their blood glucose levels regularly. Knowing blood glucose levels allow patients to alter their diabetes management strategy if the levels are not near the target.<sup>1</sup> Doctors prescribe test strips to patients with diabetes to be used as part of their care plans. It is possible that a portion of test strips paid for by Medicare and other insurers are not used by many patients. Nevertheless, patients covered by health insurance are often resupplied with blood glucose test strips whether or not they have used up their prescription. As stated by Doug Hoey, CEO of the National Community Pharmacists Association in an article by [HME News](#)<sup>2</sup>,

“We have heard stories of boxes and boxes of strips being sent to patients, charged to Medicare and the patient can’t use them fast enough,” he said. “Or the patient is deceased and the supplies continue to mount up at the home.”

Some of the unused test supplies are sold in the black market. While test strips can be legitimately purchased over-the-counter for cash price by anyone, the second-hand sale of these test strips is fraudulent if the strips were obtained through a prescription and reimbursed by Medicare/Medicaid. As such, the term “black market” is often replaced by “gray market” given the fact that selling test strips is not illegal in and amongst itself.

Awareness, outrage, and a call for action are beginning to build around the issue of the black market sale of test strips. Several local television stations have exposed the practice this year. CBS Denver was one of the first to break the story back in February 2011 with their broadcast of “[CBS4 Investigates Black Market Diabetes Test Strips](#)”<sup>3</sup> exposing “an alarming practice that has the director of one of the nation’s leading diabetes centers and journals issuing a warning to patients.” The alarming practice at the center of the report: the buying and selling of diabetic test strips on the Black Market. A practice that could ultimately cost a person with diabetes their life as recalled, expired and counterfeit strips are bought and sold daily. Only a few weeks later, KENS in San Antonio, Texas followed with [a report of its own](#)<sup>4</sup>.

According to the [2011 National Diabetes Fact Sheet](#)<sup>5</sup>, 25.8 million people in the United States are affected by diabetes with associated healthcare costs of approximately \$175 billion per year (for the year 2007). Many diabetes patients do not have adequate insurance to cover the cost of test strips. Monthly supplies for can run into hundreds of dollars. As the person with diabetes in [a Fox Baltimore report](#)<sup>6</sup> explained, “Not everybody has the kind of good insurance that I have, and this is really expensive stuff.”

[Research](#)<sup>7</sup> has shown that through proper monitoring of blood sugar levels and adherence to care plans, diabetes patients are healthier and require fewer visits to the doctor than those who are non-compliant. The importance of following strict procedures in proper diabetes care is best summarized by [William Herman, M.D., M.P.H.](#)<sup>8</sup>, one of the world’s foremost experts on diabetes, in stating, “It’s now well-proven from scientific studies that diabetes control matters, and that better sugar control over years and decades is associated with a reduced risk of complications affecting the eyes, the kidneys, the nerves, heart and

blood vessels.” Using test strips that do not meet FDA standards such as many of those sold on the Black Market can result in inaccurate data from faulty strips leading to dire consequences.

One possible solution: to account for the usage of prescribed test strips before more can be provided to the patients. This is possible, as every major provider of blood glucose meters – Abbott, Bayer, LifeScan (a Johnson & Johnson company), Nipro and Roche – has the technology to handle verification of test strip usage. However, because meters from each of these manufacturers are designed slightly differently and vendors of these supplies are faced with the onerous task of pulling the data separately for each system, a clear need exists for a cross-platform technology to bridge the gaps between manufacturers. A few companies have addressed this challenge already.

HealthVault by Microsoft® (NASDAQ: MSFT), WellDoc, and the Health-e-Connect (HeC) System by [ALR Technologies, Inc. \(OTCBB: ALRT\)](#) all are in the mobile health space and offer potential solutions to the cross-platform dilemma. Juxtaposing the technologies, however, reveals some stark differences.

HealthVault, which does not have Food and Drug Administration 510(k) clearance, is a personal health record storage solution similar to what many companies are doing in the burgeoning electronic medical records arena.

WellDoc has conducted clinical trials comparing their system to traditional practices of diabetes care by measuring A1c (the standard measure for diabetes control) with positive results. The importance of patient compliance to prescribed blood sugar testing was confirmed in WellDoc’s research to reduce A1c levels. The caveat to WellDoc’s system is that it relies on patients to manually entering data into a cell phone several times a day. Manual (user) data entry has been shown through other studies to be time consuming, inconsistent, and an inaccurate representation of actual use.

ALR Technologies’ HeC System, a chronic disease management technology, covers the complete range of compliance and documentation. The HeC System has also been successfully used in [clinical trials](#)<sup>9</sup> as part of intensive blood glucose monitoring programs. Cleared by the FDA in October for remote monitoring of patients in support of effective diabetes management programs, HeC is a cross-platform system compatible with all the major manufacturers’ blood glucose meters which allows test results stored in a meter to be uploaded. The data is organized for the respective needs of patients, clinicians, test supply vendors and insurers, whether it be encouraging patient compliance or documenting strip count for reimbursement and refill requirements. ALR’s platform also allows for mobile alerts reminding diabetes patients that it is time to test their blood glucose levels.

The Black Market offerings and the subsequent risks involved are not going to disappear on their own, nor will the exorbitant waste of funds relating to non-documented strip reimbursement. Fortunately, steps have been taken in the past to combat similar problems; such as when Medicare and many private insurers began mandating the verification of use for CPAP machines to allow reimbursement for sleep apnea. Given this precedent and the mounting awareness of strip count fraud, it is easy to envision the government taking similar actions to deal with the issues surrounding diabetes test strips. Such action would exponentially grow the usage of technologies such as the HeC System. Medicare provides coverage to 10.9 million diabetes patients and pays over \$1 billion\* a year for test strips alone.<sup>5 10 11 12</sup>

<sup>13</sup>With the financial pressures in the healthcare industry to regulate costs and provide better disease management, it would seem likely that further actions are imminent.