

White Paper

Personal Medication Adherence

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September, 2016

Abstract

Personal Medication Adherence (PMA), or lack of PMA compliance, is a \$300 billion problem in the U.S. and it bogs down our healthcare system⁽¹⁾. Patients forget to take or may confuse their medication, which can result in being readmitted to the hospital, a skilled nursing home or assisted-living facility, or with another visit to the doctor's office. Recent healthcare laws are emphasizing value-based healthcare and use of technology to improve quality of service. The advent of the Internet of Things (IoT) has brought various technologies to the forefront that, when applied to PMA devices, can help resolve some of the issues we currently face.

The Problem at Hand

Studies show that 20% to 80% of patients make errors in taking medication and that 20% to 60% stop taking medications before being instructed to do so. With older populations, compliance rates range roughly from 40% to 60%, with an average rate of less than 45%. Patients forget to take their medications, creatively alter their medication regimens, engage in unendorsed polypharmacy (taking multiple medications), mix up their medications, and take medications in combinations that may have dire synergistic interaction effects due to multiple physician prescribers. The percentage drop in medication prescribed to medication continued is alarming, as shown in Figure 1⁽²⁾.

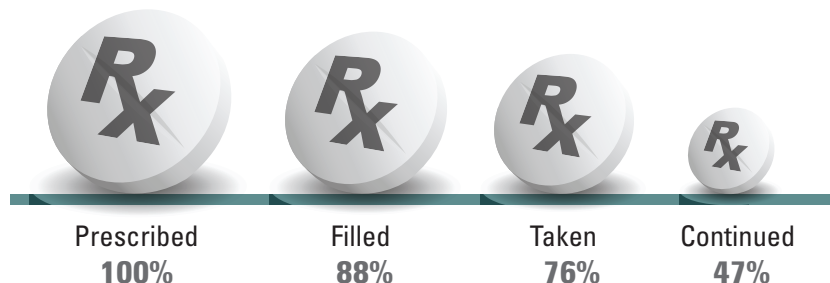


Figure 1. Medication prescribed as compared to actual medication use has dropped substantially.

Note 1: Source: <http://worldofdtcmarketing.com/non-adherence-costs-us/cost-of-healthcare-in-the-u-s/>

Note 2: Source: <http://multiple-sclerosis-research.blogspot.com/2014/02/make-sure-you-take-your-medication-poor.html>

Studies have also shown that 40% to 60% of patients could not correctly report what their physicians expected of them 10 to 80 minutes after they were provided with the information. Yet another study reported that over 60% of the patients interviewed immediately after the visit with their doctors had misunderstood the directions regarding prescribed medications⁽³⁾.

An Express Scripts report spells out the high price of medication nonadherence, stating that in 2013 alone the cost on the U.S. healthcare system due to this issue was \$337 billion. The annual deaths caused by noncompliance far exceed deaths caused by auto accidents and AIDS combined⁽⁴⁾.



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Industry Statistics

Medication nonadherence is an enormous burden to the U.S. health care system.

Poor medication adherence costs the healthcare system some \$300 billion annually due to medication-related problems, but can be mitigated, the American Heart Association says. For every dollar we spend on medication adherence in diabetes, for example, the healthcare system saves \$7. That's a 7:1 savings ratio, and the savings for hypertension and cholesterol (4:1 and 5:1, respectively) aren't far behind. Poor medication adherence is a common problem, according to The American College of Preventive Medicine (ACPM). Some 20%–50% of patients don't take their medication as prescribed for a variety of reasons, including low health literacy, cost, lack of understanding why they need the medication, and inadequate follow-up, among others, according to the organization.

Total U.S. Healthcare spending is estimated at \$3 trillion, while spending of retail prescriptions is estimated at around \$300 billion according to CMS.

According to a recent publication of the World Health Organization, the proportion of people age 60 and over is growing faster than any other age group, leading to a total population of about 1.2 billion people over the age of 60 in the year 2025.

The use of multiple medicines is considered a leading drug safety issue among this patient population because of potential drug interactions or inappropriate prescribing. National Council on Patient Information and Education (NCPPIE) data suggest four out of five older Americans live with one or more chronic conditions and two out of five report taking five or more prescription medicines.

Thus, Hippocrates' exhortation to the physician to "not only be prepared to do what is right himself, but also to make the patient...cooperate" has consistently failed for more than 2000 years.

"In the United States, it is estimated that lack of adherence causes approximately 125,000 deaths and at least 10% of hospitalizations."

*– Aja B. Williams, J.D., ONC,
Office of Policy and Planning*

"Half of the 3.2 billion annual prescriptions dispensed in the United States are not taken as prescribed."

*– Hayden B. Bosworth, Ph.D.,
Duke University Medical Center*

Note 3: Harold Gottlieb, PhD, Article in MedScape Global Medical Publications

Note 4: Source: <http://www.2brothersgiftstore.com/pilldispenser.html>

Healthcare Laws & Stakeholders

Ensuring people stay healthy and get the right care is important. However, making sure a medication regimen is adhered to is an integral part of care delivery and presents itself as an attractive business opportunity.

Pharmaceutical companies, insurance providers and pharmacies have a vested interest in patients adhering to their medication regimens. Hospitals can benefit with lower patient readmission, better medical plan ratings and lower insurance costs. For instance, under the Affordable Care Act (ACA), Centers for Medicare & Medicaid Services (CMS) are required to impose penalties on hospitals with patient readmission rates that are higher than the national average. Improved PMA rates would help lower these charges. Stakeholders are addressing this problem in their own way, and one can foresee the need for a unified solution with multi-stakeholder participation in the near future. All the stakeholders should contribute toward the cost of providing PMA solutions to patients for the greater good of healthcare.

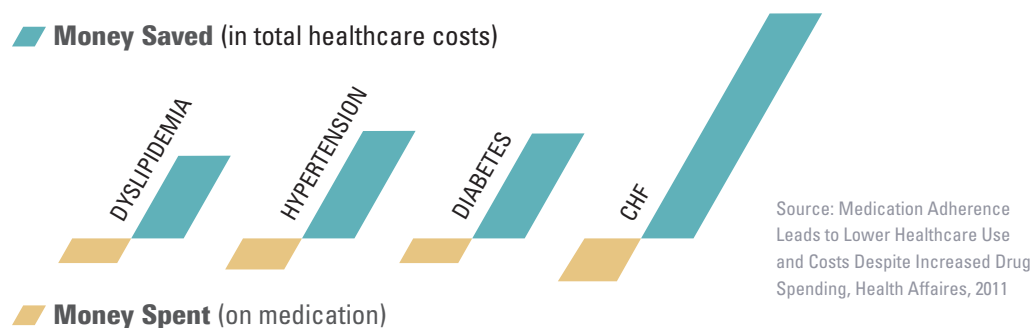


Figure 2. Preventative healthcare (proper medication) saves substantially in the long run

Recent regulatory changes and technology advancements are also driving the industry toward better systems for adherence. Service providers will be paid based on the value of the service provided and not the event, which means hospitals do not want patients to come back for the same illness (i.e., the ACA). Service providers are incentivized to use technology to lower costs and reduce readmission rates (HITECH: Health Information Technology for Economic and Clinical Health Act).

The Physician Quality Reporting System (PQRS) is a voluntary Medicare program that provides a 0.5% incentive payment to practices with eligible professionals that satisfactorily report data on quality measures for covered physician fee schedule services furnished to Medicare Part B fee-for-service beneficiaries. Many of the PQRS measures rely heavily on patient adherence.

The widespread adoption of Electronic Health Records (EHRs) has also been successful in driving medication adherence. EHRs have become the central information source in an integrated medical care environment, enabling better checks and balances. A recent study by Kaiser Permanente has shown an improved number of patients following physician recommendations on medications for chronic illnesses. Only 7% (hypertension), 11% (diabetes), and 13% (cholesterol) of those Kaiser patients receiving medical care in this “integrated” manner failed to pick up their medication. Previous studies have shown up to 22% of patients in non-“integrated” health systems neglect to fill new prescriptions.

Pharmaceutical companies will need to determine the value of incorporating EHR and, specifically, ePrescribing into their strategic marketing plans. For example, can ePrescribing be used as a means to increase adherence and brand loyalty through an ePrescribing coupon? Also, what impact will ePrescribing have on how brands engage with patients?

The ever-improving technology, meaningful use and financial incentives, and the need for operational efficiencies will continue to drive the adoption and improvement of ePrescribing and EHR systems. Going forward, EHR will provide an opportunity for pharmacies to partner with

institutions by encouraging them to use EHR data to identify where patients are in their treatment and help determine what could be done to help them increase adherence.

Patient education is another key factor. CVS Caremark recently partnered with Dovetail Health, a provider of transitional care services, to help prevent hospital readmissions, stating that helping patients better manage and understand their medication regimens after they are discharged from a hospital can play a large part in reducing the likelihood of readmissions. To that end, Dovetail is providing plan members with in-home medication counseling focused on medication adherence and drug safety.

Hospital Costs

The ACA requires the Centers for Medicare & Medicaid Services (CMS) to impose penalties on hospitals whose readmission rates for heart failure, heart attack, and pneumonia are worse than the national average. CMS has announced that two thirds of the hospitals in the U.S. would be assessed the penalty in the form of reduced Medicare payments. With nearly one in five Medicare patients returning to the hospital within 30 days, many institutions could improve their readmission rates through improvement in their patients' adherence to treatments recommended at discharge⁽⁵⁾.



Figure 3. Nonadherence leads to higher readmittance rates and expenses at hospitals

Hospitalization costs also increase dramatically due to nonadherence. In a recent study by Healthentic of over 100,000 patients with either diabetes, high-blood pressure or high cholesterol, only half of whom were judged adherent, the avoidable cost of hospitalizations was \$8.6 million.

In a report funded by the Anthem Foundation and completed in partnership with the Foundation, Anthem Blue Cross in California, and Anthem Blue Cross Blue Shield in Connecticut, and supported in part by a grant from the California Health Care Foundation in Oakland, Calif., it was found that readmissions lead to an estimated \$41.3 billion in additional hospital costs each year in the U.S., and hospitals and health systems are being held accountable for this financial burden through new payment models, such as accountable care organizations, and through penalty programs, such as the CMS' hospital readmission reduction program (Source: report from the Network for Excellence in Health Innovation (NEHI)).

In 2011, roughly 20% of Medicare patients (nearly 2 million people) were readmitted to a hospital within 30 days of discharge, though it is estimated that 75% of these readmissions could have been prevented with an annual savings to Medicare of \$17 billion. As a result, the Medicare Hospital Readmissions Reduction Program (HRRP) was created within the ACA of 2009. Medication management and lack of patient engagement in their care constitutes the largest percentage of readmissions.

Note 5: Source: Michael C. Sokol, MD, MS, Kimberly A. McGuigan, PhD, Robert R. Verbrugge, PhD, and Robert S. Epstein, MD, MS, Impact of Medication Adherence on Hospitalization Risk and Healthcare Cost, Medical Care • Volume 43, Number 6, June 2005.

Recommendations from the Network for Excellence in Health Innovation and Anthem include making real-time, comprehensive and accurate patient medication adherence data available at all points of care an explicit goal.

Home care Advancement in mobile technology is pushing point of care from hospital to home. Causes of nonadherence in home care patients include confusion of medications and regimens, cost of prescriptions, forgetfulness, and questions of need. There is also a lack of skilled oversight and patient engagement. 80%-90% of people requiring care in the U.S. receive it from family members or friends. Using home-delivery methods increases medication adherence by 19%, and by 28.5% when paired with Express Script's advanced adherence solutions.

Assisted living The situation here is similar to home care; however, there may be some patient engagement interaction, but no skilled oversight or assistance. Medications are typically ordered through an individual's retail pharmacy of choice. Assisted-living facilities are looking for beneficial medication management systems to enhance their resident care and extend the time clients can enjoy the freedom of independent living before transitioning to more restrictive and more expensive skilled nursing environments. The ability to stay "at home" or move to facilities with more assistance and care is highly dependent on the individual's ability to manage their medications as prescribed.



Telehealth Monitoring of vitals and patient engagement is a burgeoning industry, but there is no medication oversight or reliable adherence information. Telehealth organizations may be well positioned to provide monitoring and call center services to enhance medication adherence. URAC® has developed accreditation standards that will ensure not only professional standards, but uniformity of information and interactions between providers, payer organizations and patients.

Pharmacy Engagement Due to the number and variety of medications taken by polypharmacy patients, it is necessary for a single pharmacy to manage all prescriptions to protect patients from potentially over-medicating and adverse drug interactions. Pharmacies can play a critical role by being the middleman between the patient and the doctor or hospital; thus, improving adherence rates.

PMA and Technology (IoT)

The Internet of Things (IoT) has enabled the various components of the medical ecosystem to be connected, as shown in Figure 4⁽⁶⁾. Major companies are recognizing the potential market and are introducing clever PMA devices, such as the med-ic® Electronic Compliance Monitor (ECM®) and e-pill® automatic pill dispenser, which will help patients track medicine usage and alert them

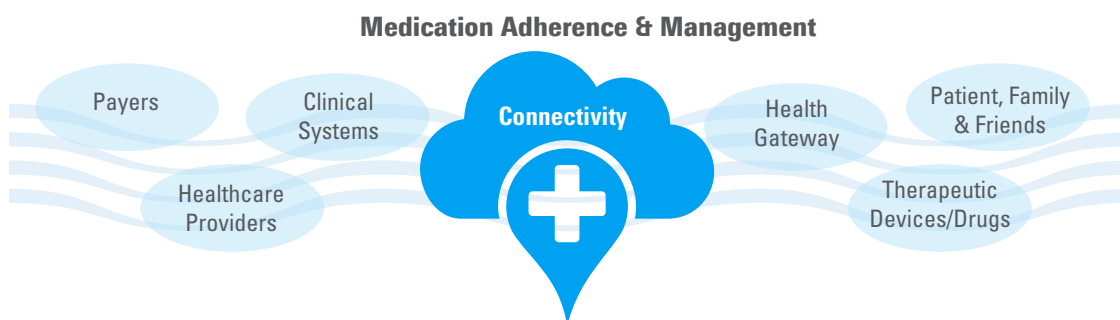


Figure 4. PMA Solution Components

Note 6: Source: <http://www.s3group.com/connected-health/solutions-development/>

when it is time to take their medication. These devices help patients avoid taking the wrong medication and may also have automatic refill ordering capability. Advances in sensors, processors, wireless/efficient charging, wireless connectivity, cloud infrastructure and mobile apps provide a reliable and cost-effective way for product designers to implement PMA devices.

Technology is helping drive patient behavior toward improved adherence in various ways. For example:

- **Sensing** – Sensors allow for automatic detection of when medicine is taken or not taken. They can also track the quality of the medicine by measuring environmental exposure.
- **Wireless Connectivity** – Leveraging Bluetooth® Smart communications, PMA devices can connect to the cloud without any clumsy wires. Mobile applications allow patients to self-manage the required interactions, scheduling, and event acknowledgements via smartphones. For instance, the mobile applications would communicate with the pharmacy cloud via an Internet connection (cellular or Wi-Fi) to upload adherence data and receive medicine pack Radio Frequency Identification (RFID) validation information.
- **Mobile Devices** – Smartphones and tablet devices provide an easy gateway to the cloud and personal alert system. Automated event alerts and notification can be made via text messaging or phone calls to patients, caregivers, doctors and family members to assist in adherence, engagement and education.
- **Mobile Applications** – Intuitive mobile apps empower patients to manage their personal healthcare on mobile devices.
- **Cloud Infrastructure** – Cloud-based platforms allow physicians to communicate quickly, efficiently and securely with each other and their patients to provide improved understanding of their conditions and their often complex drug regimens.

Technological advances from the IoT are enabling a new class of PMA devices that are easy to use, affordable and keep the patient involved in monitoring their own health as shown in Table 1. This is truly a case where technology is helping to solve a real problem, and the statistics will speak for themselves as we make further progress.

Table 1. Electronic Telehomecare devices

Type of Device	Special Features
Medication Alert Watch	Vibrating alarm signals patient to take pills
Blister pack	Scanned by a reader and data uploaded to a computer; reports when each pill is removed
Smart pill container	Microchip in cap sounds an alert and transmits a notice to a computer that the cap was opened
Multi-compartment pillboxes	Alert function and reporting function that uploads data to a computer
Mobile technology App	Visual and audible medication dose reminders; patient reports back to clinic when “medication taken”
Mobile technology App	Electronic health record and e-prescribing tool provides mobile access for clinical medication management

Renesas Personal Medical Adherence Reference Solutions

Solution 1. Smart Connector Model

The Smart Connector model (Figure 5) was designed while keeping the requirements of a small form factor and low development cost in mind. The blister pack to be used with this model needs to have traces printed on the back foil. The user interface and setup is very simple and intuitive. The blister pack clips on to the smart connector and the device is ready to be powered up.



Figure 5: Smart Connector with Printed Foil Blister Pack

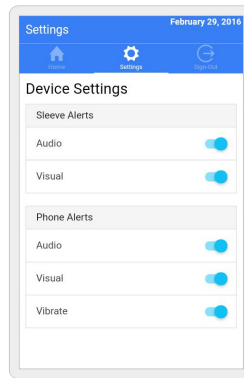


Figure 6: Mobile App Screenshots

On the mobile phone side (Figure 6), the user logs into the app and enters the prescription information (blister pack ID, time table of dosage). Once that is done, the phone has to be paired via BLE to the smart connector. Every time a new blister pack is inserted, it will be authenticated against the mobile app. When it is time to take a dose, the smart connector will give an audio alert and the LCD screen will display the blister number from which the dose has to be taken. The mobile phone can also be set up for visual, audio or vibrate alert(s). Whether the user pops the blister or not, when it's time to take the medicine, the action will be logged into the mobile app data log.

Wireless and USB charging capabilities are provided for flexibility along with fuel-gauge function for the battery. Temperature and humidity sensors monitor environmental exposure for the medicine. A summary of all the features is listed in Table 2.

Table 2. Renesas Smart Connector Solution

Features	Benefits
Printed traces on blister pack back foil	Auto detect of which blister was popped to track medicine adherence
Qi Wireless Charging	No-hassle charging to enable quick and repetitive usage
Fuel Gauge	Accurate measure of the battery charge to avoid shutdown
Alert	Audio alert to indicate it is time to take the medicine
USB Charging	Standard micro-USB charging for additional charging method
RFID on Blister Pack	Authenticate blister pack type and serial number to the prescription to avoid error
Bluetooth Smart (BLE)	Secure, reliable and low power method to communicate to the mobile device
Temperature Sensor	Ensures medicine has not been subjected to extreme conditions
Humidity Sensor	Ensures medicine has not been subjected to extreme conditions
LCD Screen	Displays blister number to take meds from for current dose, battery remaining percent, time to next dose, charging status
Touch Buttons	Clear alert, select display options
Mobile App	Enter prescription and patient information, authenticates user and blister pack, alerts for reminder to take medicine, adherence log to be reviewed by pharmacist or doctor

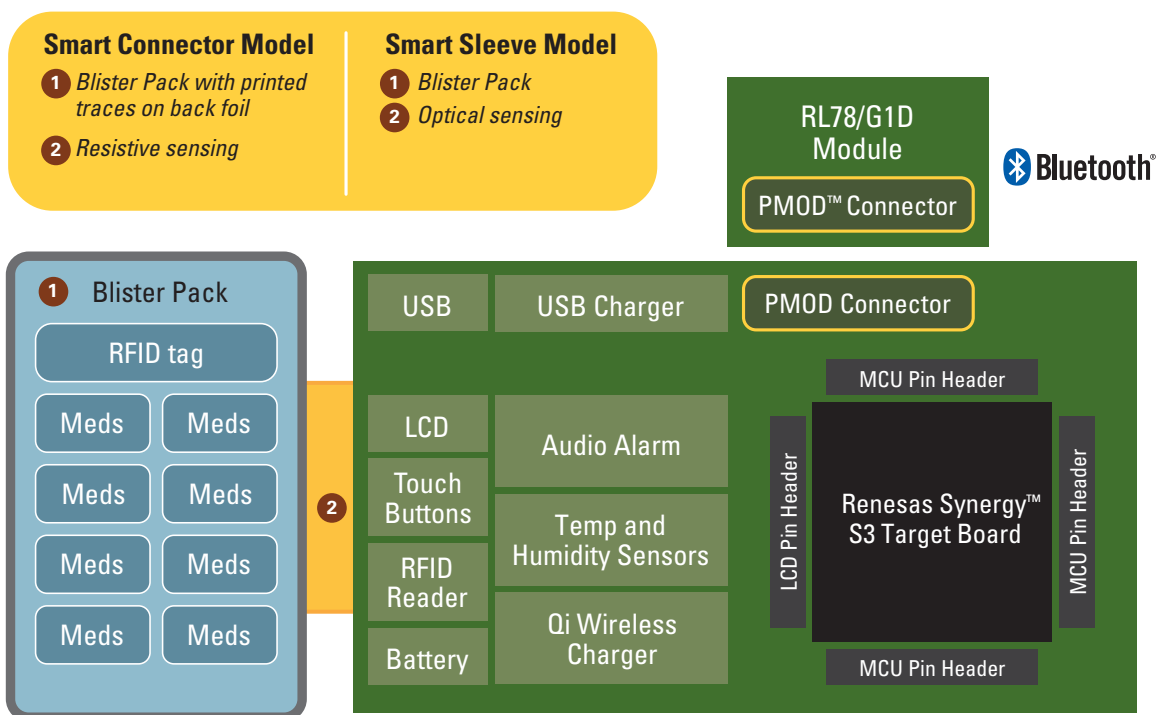


Figure 7: Smart Connector and Smart Sleeve configurations.

Solution 2. Smart Sleeve Model

The Smart Sleeve model (Figure 8) was designed for elegance and compatibility with off-the-shelf blister packs. The user interface and setup is very simple and intuitive. The blister pack slides into the smart sleeve and the device is ready to be powered up.

On the mobile phone side (Figure 9), the user logs into the app and enters the prescription information (blister pack ID, time table of dosage). Once that is done, the phone has to be paired via BLE to the smart sleeve. Every time a new blister pack is inserted, it will be authenticated against the mobile app. When it is time to take a dose, the smart sleeve will give an audio alert and the LCD screen will display the blister number from which the dose has to be taken. The mobile phone can also be set up for visual, audio or vibrate alert(s). Whether the user pops the blister or not, when it's time to take the medicine, the action will be logged in the mobile app data log.



Figure 8: Smart Sleeve with Blister Pack

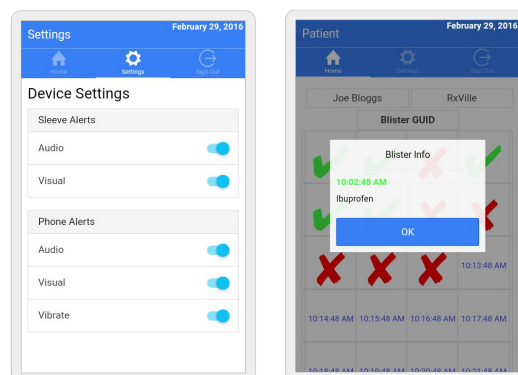


Figure 9: Mobile App Screenshots

Wireless and USB charging capabilities are provided for flexibility along with fuel-gauge function for the battery. Temperature and humidity sensors monitor environmental exposure for the medicine. A summary of all the features is listed in Table 3.

Table 3. Renesas Smart Sleeve Solution

Features	Benefits
Optical Sensing	Auto detect which blister was popped by finger detection to track medicine adherence
Qi Wireless Charging	No-hassle charging to enable quick and repetitive usage
Fuel Gauge	Accurate measure of the battery charge to avoid shutdown
Alert	Audio alert to indicate it is time to take the medicine
USB Charging	Standard micro-USB charging for additional charging method
RFID on Blister Pack	Authenticate blister pack type and serial number to the prescription to avoid error
Bluetooth Smart (BLE)	Secure, reliable and low power method to communicate to the mobile device
Temperature Sensor	Ensures medicine has not been subjected to extreme conditions
Humidity Sensor	Ensures medicine has not been subjected to extreme conditions
LCD Screen	Displays blister number to take meds from for current dose, battery remaining percent, time to next dose, charging status
Touch Buttons	Clear alert, select display options
Mobile App	Enter prescription and patient information, authenticates user and blister pack, alerts for reminder to take medicine, adherence log to be reviewed by pharmacist or doctor

Optional Enhancements

Renesas developed these solutions to show proof of concept and give customers a head start for designing world-class products. This solution showcases the Renesas Synergy™ Platform featuring the Renesas Synergy S3 MCU, RL787/G1D Intelligent Bluetooth Smart MCU and the USB Charger IC.

Renesas Synergy is a complete and qualified platform that accelerates embedded development, inspiring innovation and enabling differentiation. The RL78/G1D is an industry-leading, low-power Bluetooth Smart v4.1 MCU. Renesas has a portfolio of USB battery charger ICs.

Customers have the option to use wireless or cellular technology for connectivity instead of the provided BLE function. The mobile app can be further enhanced by providing back-end connectivity to a cloud platform and building a dashboard in the cloud. These dashboards can be a single point of interaction between the doctor, pharmacy and patient.

Conclusion

The global medication adherence systems market is increasing significantly due to the growing awareness of the health and financial aspects to all stakeholders; identified chronic conditions such as diabetes, CHF and HIV; and a growing geriatric population.

As per the United Nations Department of Economic and Social Affairs (UN-DESA) report on the global aging population, the population of people aged 60 years or above is expected to reach 21.1% by the end of 2050.

Furthermore, the evolution of mobile health (mHealth) technologies and increasing demand for personalized healthcare technologies are also driving the growth of the global medication adherence market.

The chronic underuse of medications is one of the most common forms of nonadherence. According to the CDC, the nonadherence of drug therapy causes 30% to 50% of treatment failures and leads to 125,000 deaths annually.

The HITECH Act has provided more than \$35 billion in incentives to healthcare organizations. More than 30% of clinical settings now utilize EHRs. It is estimated that HITECH incentives will boost EHR adoption rates to 90% by 2019. This creates a uniform infrastructure for data acquisition and analysis, which will enhance and promote technology solutions to the problem of nonadherence.

There are many stakeholders who will rely on the improved outcomes and benefits of adherence including patients, healthcare providers, payers, pharmacies and pharmaceutical manufacturers. For example, the U.S. pharmaceutical industry loses an estimated \$188 billion annually due to medication nonadherence. Hospitals face penalties for readmissions when an estimated 38% are caused by nonadherence to medications after discharge.

Visits to doctors and emergency rooms, admissions to assisted living and skilled nursing facilities and deaths could all be drastically reduced if medication adherence were improved.

Through new secure technologies for data collection and pervasive smart phone and other intelligent devices for communications and user-facing applications, a widespread community of patients can be assisted, thereby saving lives, improving health, and dramatically reducing the costs of healthcare.