

# Background

Beginning in 2011, the Centers for Medicare and Medicaid Services (CMS) developed Electronic Health Records (EHR) Incentive Programs to encourage eligible professionals and hospitals to adopt, implement, upgrade (AIU) and demonstrate meaningful use of certified EHR technology.

As of October 2015, more than 479,000 health care providers received payment for participating in the programs. CMS published a final rule that specifies criteria that eligible providers must meet in order to participate in the Incentive Programs in 2015 through 2017.

Through these EHR Incentive Programs' requirements (Modified Stage 2 and 3), CMS stresses advanced use of certified EHR technology to support health information exchange and interoperability, advanced quality measurement, and maximizing clinical effectiveness and efficiencies.

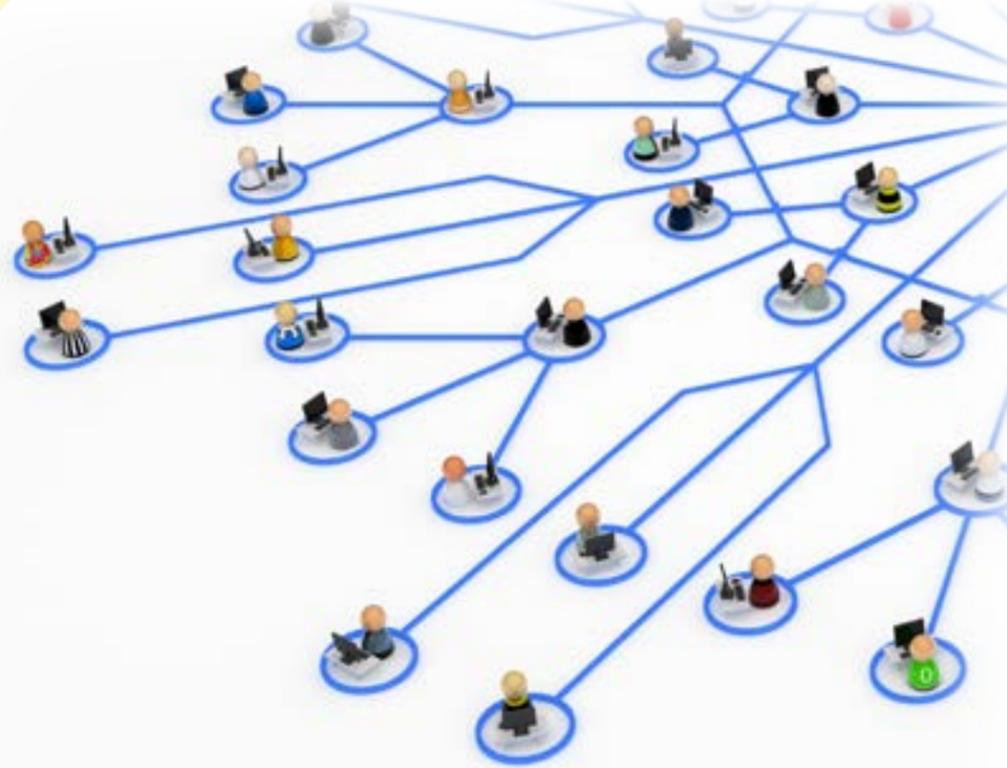
The lingering question surrounding all of this technology and exorbitant cost is:

## What truly defines clinical effectiveness and efficiencies?

CarePICS® fulfills this requirement through standardizing acquisition and interpretation of imagery measurements supporting a customizable protocol and formulary management system that optimizes clinical decisions.

EHR systems serve as a repository for clinical data, subsequently, CarePICS® provides a patient encounter tool that offers clinician formulary suggestions from an enterprise configured protocol for proper wound therapy, which is complemented by a machine learning algorithm that alerts users to the success of therapies over time.





## The Product

### Systemness®

powered by

CarePICS® represents Population Health Management for Wounds throughout the care continuum. This telehealth solution delivers a user-friendly client application with a uniquely configurable cloud-based architecture.

**The term “Systemness” refers to the seamless integration of assets and services within a healthcare system to deliver quality care to patients and value to stakeholders.**

Systematic changes to behavioral and activity-based processes are the typical methods used to produce positive outcomes within organizations.

Our approach to population health management with pioneering wound measurement technology and customizable protocol-formulary management is unmatched in the industry.

## Clinical Needs

According to a 2014 report, over 8 million Medicare beneficiaries suffer from chronic wounds and total Medicare spending estimates for all wound types are \$28.1 billion (low-range estimate), \$31.7 billion (midrange estimate) and \$96.8 billion (upper-range estimate). Additionally, Diabetes and Critical Limb Ischemia (CLI) rates continue to grow in our aging population and CLI intervention patients can have up to 56% readmission rate; 50% are from wound care complications alone.

A simple Population Health Management solution is central to enabling clinical collaboration for decision making that impacts quality patient care. CarePICS® fulfills this requirement. Numerous state Medicaid and private insurers currently reimburse for telehealth visits and Medicare is likely to as well in the near future. Telehealth opportunities are numerous and expanding for wound care, dermatology, neurology and many other clinical applications.

**Agency for Healthcare Research and Quality reports that the average costs of one Medicare patient readmission averaged \$13,800 in 2013.**

Value-based reimbursement models from Medicare and Medicaid are compelling care providers to reduce overall costs while standardizing care, monitoring patients throughout the care continuum and evaluating practices to maximize positive outcomes and patient satisfaction.



# Logic Tree for Wound Care

The current standard for protocol and formulary configurations consists of static programs embedded into EHR systems. The ability for clinical enterprises to make dynamic decisions based on live data is limited. More so, proper adherence to a current and uniform formulary is difficult. Currently, medical staff are provided hardcopy protocol and formulary schemas that are ambiguous and dated.

A novel concept in this operation is a control system utilizing customizable trending, protocol and formulary functions integrated with a planimetric imagery algorithm to determine wound dressing efficacy. The CarePICS® logic tree is a Python-based program that interfaces with a PostgreSQL database in order to support a REST based API.

This interface allows for iPhone, Android and Web Application clients to first populate a visual chart for a user to fill out on behalf of a patient, then send the chart data to the server in real-time using the charting API, which finally results in a two-way socket response to update the client's chart with a proposed treatment solution using the formulary logical operators.

The CarePICS® logic tree algorithm uses a number of customizable clinical chart fields with a series of drop downs in order to formulate a recommended treatment method for a patient that is specific to that clinical enterprise's needs.

The algorithmic treatment determination compares a number of logical operators to produce a resulting primary and secondary treatment option. Users select treatment options from an assortment of medical products

that exist inside of our database and outside the influence of an individual user's decisions. This creates a clinical chart input method that may vary immensely between clinical enterprises but produces a medical product outcome that easily replicates within an enterprise.

All of the customizable chart fields exist in a specific database table for a given enterprise. Each series of formulary combinations resides in the

enterprise's database under a formulary table that contains rows of formulary options. When a mobile application user selects a series of chart values within the application, the server runs a formulary database lookup using the chart fields that user selected in order to find a formulary table-row case that matches the user's input. The case matching begins with the most specific and works backwards to match off with the least specific.

## Image Capture and Measurement

CarePICS® supports a wound imagery capture tool that functions on any smart device operating Android or iOS systems. The feature contains a planimetry algorithm utilizing a reference phantom that yields very accurate measurements of wound surface area. Primary or secondary users can trace the edges of wounds on the device screen to define this measurement. The accumulation of images and measurements from successive clinical sessions generate trends to account for change over time. A supplementary web services application administers all relevant clinical data for comparison.

"According to the Wound Healing Society's guidelines, "if ulcer does not reduce by 40% or more after 4 weeks of therapy, re-evaluate and consider other treatments". Indeed, as described by Sheehan et al., the percentage of wound surface reduction to

4 weeks is a strong predictor of healing at 12 weeks. In a retrospective study by van Rijswijk et al., shows that the reduction of ulcer surface by 40% or more during the first 4 weeks is a positive predictor for healing.

It's accepted that a 50% decrease in size after 6 weeks is a sensitive predictor (93% sensitivity) to complete healing at 12 weeks. As the consecutive measurements are compiled in the application and available as a graphic, the mobile solution gives the care provider some critical information about wound healing evolution and prognosis.

*Baseline wound area :*  
*current wound area / baseline wound area =*  
*% change over time*

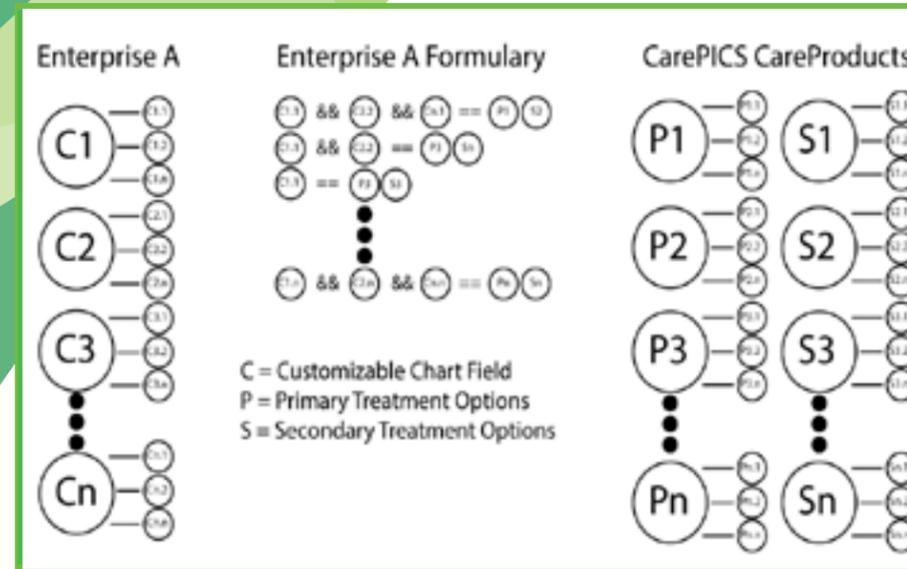
# Wound Determinant Protocol

Few clinical enterprises subscribe to a universal protocol based on specific wound determinants. While a single entity considers several key criteria to be instrumental in defining a formulary choice, others may require different solutions. CarePICS® affords a clinical end user a configurable protocol defined by wound determinant categories. The wound determinants categories (wound state, wound type, tissue type, drainage and drainage type, pain, odor, etc.) contribute to building a custom clinical profile specific to any entity.

Clinical support personnel highly trained in wound assessment and etiology construct this profile via the user-friendly web services application. After database implementation, the wound determinants within the chart section of the mobile application can prompt lesser-trained clinicians with the proper formulary choices for advanced wound care products.

## Formulary Management

Formularies aggregate from primary and secondary therapy categories (absorptive, bactericidal, bacteriostatic, enzymatic, foam, hydrocolloid, hydrogel, NPT, occlusive, etc.), which determine the type of advanced wound care product. However, not all clinical enterprises agree on what specific categories are necessary for a certain formulary. CarePICS® formulary choices are configurable for each custom clinical enterprise. The system can interface with a contracted supplier database and implement a method for selecting specific product offering to meet clinical and economic benchmarks. This process accounts for pre-negotiated manufacturer/supplier contracts for products at certain costs. Every series of formulary combinations exists in the clinical enterprise's database under a formulary table that contains rows of formulary options. After system integration, the server runs a formulary database lookup using the mobile application chart fields the user selects in order to find a formulary table row case which matches the one the user inputs. The case matching starts with the most specific and works backwards to the least specific.



*Enterprise A hosts n custom chart fields and each of these custom chart fields have n number of selectable options.*

*When creating the formulary, Enterprise A can combine some or all of the selectable options to create a logical tree of resulting CareProducts.*

*Resultant CareProducts display universally by the database and remain a static list of selectable treatment options to the users.*

In the graphic above, Enterprise A hosts n custom chart fields and each of these custom chart fields have n number of selectable options. When creating the formulary, Enterprise A can combine some or all of the selectable options to create a logical tree of resulting CareProducts. Resultant CareProducts display universally by the database and remain a static list of selectable treatment options to the users.

The analysis of wound care products' comparative efficacy produces cost savings and better population management for an organization. Specific reports are available to profile the value of product selections within the formulary. CarePICS® emulates the unique model defined in a white paper study conducted at Riverside Healthcare in Kankakee, Illinois.

The logic tree interfaces with the trend algorithm to determine over time the efficacy of chosen protocol and formulary configuration. Additionally, the trending algorithm alerts users to regressive or stalled wound healing cycles for further clinical overview. approach allows earlier intervention in treating specific patients with alternative regimens.

Decision models are reliable and effective techniques that provide high classification accuracy with a simple presentation of gathered knowledge. These structures drive numerous different areas of clinical determinations. CarePICS® is the first company to utilize an exceptionally accurate algorithmic-based imagery measurement tool coupled with logic-based analytics to provide optimized clinical and economic outcomes. This is truly a disruptive technology offering.