

DOCKETALARM.COM

CSCS Service White Paper

The CONTROLLED SUBSTANCE CONTROL SYSTEM (CSCS)

*A national, centralized system that creates new efficiencies
in the delivery of prescriptive drugs.*

Presented by:

CSCS Enterprises, Inc.
Houston, TX 77077

September 10, 2001

CSCS Confidential Document

The CONTROLLED SUBSTANCE CONTROL SYSTEM (CSCS)
A national, centralized system that creates new efficiencies in the delivery
of prescriptive drugs

The Healthcare industry is facing a number of challenges today unlike ever faced before. An educated, consuming public has ever increasing expectations for exponential improvement in Healthcare delivery, while at the same time, economic pressures are forcing tighter controls over cost, efficiency and quality.

No member of the healthcare value chain is immune from this scrutiny. The industry has widely recognized a need for better efficiencies. Federal pressures such as the Healthcare Information Portability and Accountability Act (HIPAA) mandate making the exchange of information more ubiquitous, secure and efficient. Focus is also being placed on spiraling cost structures, with efforts to improve mitigation of risk, provide more efficient billing and business modeling, eliminate redundancy, improve informational flow and lessen system abuse.

There is no one solution that will address these many challenges. Standards and guidelines such as those in HIPAA will help immensely with Informational Flow, and the Healthcare Informatics industry is focused on building support to address these needs into their products. This is driving both a new investment cycle into the Healthcare Industry, while at the same time creating a more complex set of needs that will need to be addressed in order to realize their true value of these efforts. HIPAA, while adding clear, important and necessary support and standards in the use of healthcare informatics, doesn't provide vehicles that can substantially create entire new efficiencies within healthcare, but actually help enable them.

One area where there is substantial opportunity to impact the delivery of healthcare is associated with prescription drugs. The DEA estimated that Rx drugs were sold for \$25 billion in 1993 compared to an estimate of \$31 billion spent on cocaine. Since that time prescriptions have risen over 50%, totaling close to 3 billion prescriptions annually. With soaring costs, the costs of prescription drugs is currently greater than \$50 billion annually, with limited ability to control or manage those costs.

Over 4 million people a year in the U.S. misuse or abuse prescription drugs. According to an August 1999 article in the Journal of the American Geriatrics Society, Older Americans (age 65 and older) currently account for 12.5% of the total US population, but consume 25% of all prescription medications. It is documented that 17% of the senior population misuses medications, accounting for approximately \$2 billion loss annually. The AMA estimates that 5% of physicians are grossly negligent and 1-1.5% are dishonest in their prescribing. This would amount to a cost of \$2.5 billion annually. 350,000 adverse medication errors (probably far greater not reported) occur each year among .5 million nursing home residents in the US. 1 employee in 10 has a problem with alcohol/drugs. Absenteeism is 66% higher among drug users. Health benefit utilization is 300% higher among drug users. Disciplinary actions are 90% higher among drug users. 47% of work-place accidents are drug related. Employee turnover is significantly higher among drug users.

Confidential

2

These estimates are for the cost of drugs themselves, and don't include many of the tangential costs associated with this abuse; additional healthcare required and costs associated with drug interactions, insurance fraud resulting from purchase of class drugs for resale on the street, dispensing of wrong prescriptions due to misread prescriptions, which are proportional greater.

CSCS is a healthcare utility that can assist substantially in reducing these misused and abused prescriptions that can account for a savings of over \$4 billion annually. CSCS enables major changes in the delivery of prescription drugs, with measurable social and economic impacts on spend within the healthcare value chain (less abuse-related healthcare costs, fewer erroneous prescriptions, more accountability, better tracking and management of prescriptions). CSCS creates a secure and private, independent, Internet-based, centralized system for tracking and managing prescription information in *aggregate*, allowing electronic querying and real-time notification of patient's prescription history at the time of prescription creation. This information is accessible within a controlled and appropriate context for use by healthcare professionals involved in the delivery of care to that patient.

Consumers: The consuming patients get the most value out of CSCS. They will have a comfort knowing that their physician and other healthcare professionals involved in their care will have secure and private access to historical information about their active and inactive prescriptions that can create problems or interactions. CSCS will allow consumers and their physicians to better manage the patient's prescriptive plan, lessening risk of misuse and counter-indications.

Doctors: Physicians and other healthcare providers are at risk every time they prescribe a drug. These physicians, seeking to provide their patients the best possible healthcare possible, have not current vehicle for ensuring they have an accurate view of their patients' use of prescription drugs. Information about prescriptions from specialists or other referral services may not be communicated appropriately. Patients may not remember prescriptions they are taking, forgetting about them completely or not being able to pronounce them. Patients with regular prescription patterns can empower physicians to proactively deal with potential abuse problems. It can also provide audit information that helps protect the professional from lawsuits and other potential liabilities.

Pharmacies: Pharmacies require a more precise method of monitoring the efficiency of the distribution of the over 3 billion prescriptions they fill each year. With the number of chain pharmacies having now risen to 35,000 stores, their ability to provide the highest quality service is placing a strain on staffing and the delivery of rapid, timely and accurate product. Pharmacists are constantly challenged to circumvent duplication, abuse, fraud, and misuse of these medications while providing a cost effective medication delivery system.

Adding to this complexity is a geographically expanding available pharmacopoeia, which exponentially raises the risks of negative drug interactions and its associated destructive medical outcome. CSCS can flag these issues in "real time" preventing or minimizing their occurrences.

Hospitals: Hospital therapeutics requires administration of medications on an acute and sub-acute basis with little or no knowledge of patient's outpatient medication profile. The CSCS System provides this vital data in a manner that will change the hospital medication delivery system in a dramatic fashion. This immediately reduces costs, adverse drug reactions, and eliminates the risks of facilitating drug abuse and misuse.

The CSCS system reduces or eliminates reliance on poorly trained pharmacy technicians or assistants in ensuring compliance with the regulatory agency demands in the accurate delivery of pharmaceuticals.

Pharmaceutical Providers: The Pharmaceutical Industry is in a constant race to provide the public with pharmacological formulations that are compatible with constantly evolving therapeutic formulations, and whose availability is being accelerated by the rapid expansion of effective clinical trials and research protocols.

The industries ability to respond effectively to the competitive as well as regulatory demands is challenging because of the difficulty in realizing real or near term information access and tracking information. This responsibility requires an ongoing current database of pharmaceutical demands, immediate identification of adverse reactions, and recognition of the costly development of redundant pharmaceutical products.

CSCS provides the Pharmaceutical industry with a vehicle to help them track and access appropriate information about prescriptive drugs. It provides the Industry with services which will assist in better planning, real time assessment and forecasting of regional pharmaceutical demands, helping to prevent essential medication shortages or unavailability. As well as timely recalls can be affected when focused Adverse Drug Reactions occur.

Insurance Companies/Government: Government Agencies, Insurance Companies, Veterans Administration Medical System, Workers' Compensation Providers, Private Third Party Payers, and Health Maintenance Organizations will find new efficiencies by utilizing CSCS. Even the pending new Medicare Programs, which include Pharmaceutical programs, can be brought to public availability with the comprehensive management support that is lacking today. CSCS removes many of the management limitations that affect such efficiencies and will help control costs of program delivery. All of these entities can have immediate access to potential medication abuse by identification of needless prescription duplications, potential drug interactions, and multi-source interstate prescription abuse. CSCS likewise recognizes fraudulent prescriptions as well as immediately documenting the most cost effective form of a prescribed medication.

In addition, the significant reduction in adverse outcomes due to pharmaceutical drug interactions and misuse reduces the medical costs necessitated in providing the resulting therapies.

Healthcare Informatics Providers: Industry standard XML Interfaces, and, potentially, secure access applets, will allow informatics providers to integrate their products and services and "include" CSCS access and use in a seamless fashion. The

intent of CSCS is not to dis-intermediate software or service providers in the market, but create an independent utility service that adds value to their products while achieving public good.

UTILITY STRUCTURE

CSCS is an independent information utility that acts as the central service center for the management of Prescription drugs. By allowing ready access to appropriate information at various points within the prescription process, CSCS helps to protect the patient from a variety of potential risks associated with the prescription of drugs, creates an audit capability that can help protect the healthcare professional, while eliminating significant financial overspend due to information gaps and misuse.

While operated as a for-profit entity, the CSCS Utility will expect a representative group from the various healthcare value chain members to act as an oversight organization to ensure acceptable levels of information security, access and protection. CSCS creates an independent, non-affiliated entity to act as the information liaison between all members of the healthcare community.

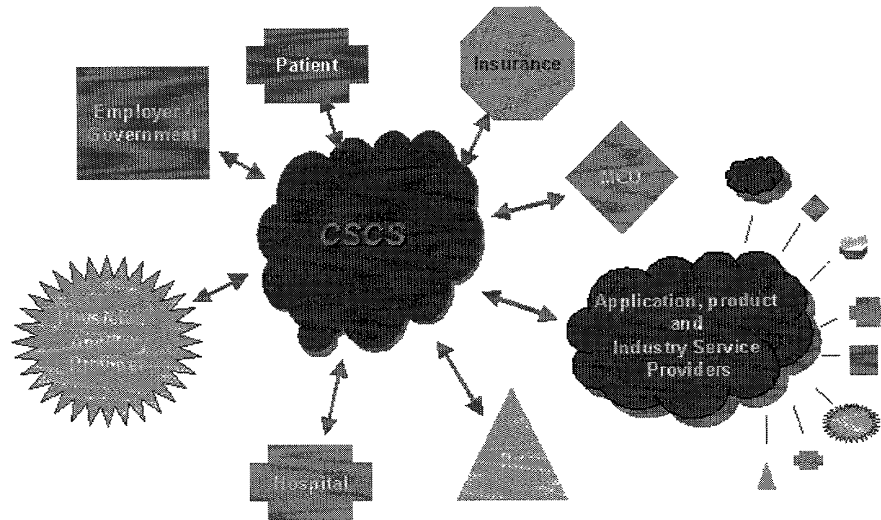


Figure 1: CSCS is an informational liaison to the healthcare community.

CSCS provides its services through technology. It consists of a data store that is maintained within a specific informational schema. Access to the appropriate information takes place through a variety of secure interactions between CSCS and various healthcare applications (or via the World Wide Web). CSCS system components will all meet or exceed HIPAA guidelines.

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.