

A Secure MTMP System

June 2007

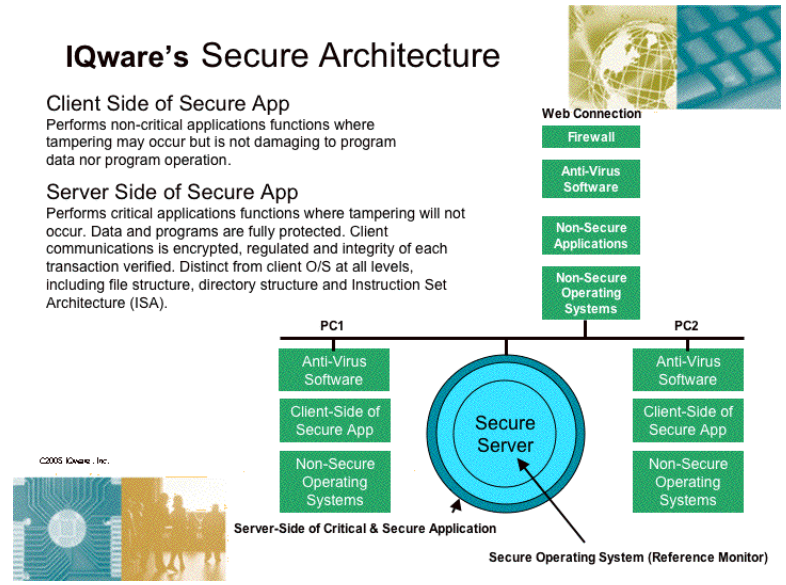
Dr. Steve G. Belovich
Mr. Donald L. Seddon



IQware's Secure Architecture

Client Side of Secure App
Performs non-critical applications functions where tampering may occur but is not damaging to program data nor program operation.

Server Side of Secure App
Performs critical applications functions where tampering will not occur. Data and programs are fully protected. Client communications is encrypted, regulated and integrity of each transaction verified. Distinct from client O/S at all levels, including file structure, directory structure and Instruction Set Architecture (ISA).



MTMP Regulations & Guidelines

(Medication Therapy Management Plan)

■ Operational Requirements

- Pharmacists are statutorily recognized, compensated and regulated for MTM.
- Medicare “Part D” drugs are targeted for verification of optimal usage.
- Adverse drug effect and interaction(s) specifically targeted.
- Plan sponsor must cooperate with licensed pharmacists & physicians.
- Chronic disease(s) which require ongoing drug therapy are targeted.
- Eligibility cost threshold is \$4,000 per patient per year now - this may change.
- Flexibility in plan development and execution is encouraged by CMS.
- Innovation is encouraged by CMS.
- Plan evolution and “best practice” development are encouraged by CMS.
- Time and resource tracking required.
- Reporting is required.
- Audit trail is required due to the overlap of HIPAA and definition of an electronic medical records.



MTMP Strategic Goals

(for Regulatory Compliance)

- Better patient care.
- Increased Pharmacist involvement
- Increased Physician involvement
- Better reporting and communication
- Electronic prescribing & seamless integration
- Accurate and efficient performance tracking
- Error prevention and detection
- Set and define “best practices” by being the “gold standard” leader
- Accurate reports to providers for proper and timely reimbursements
- Efficient implementation



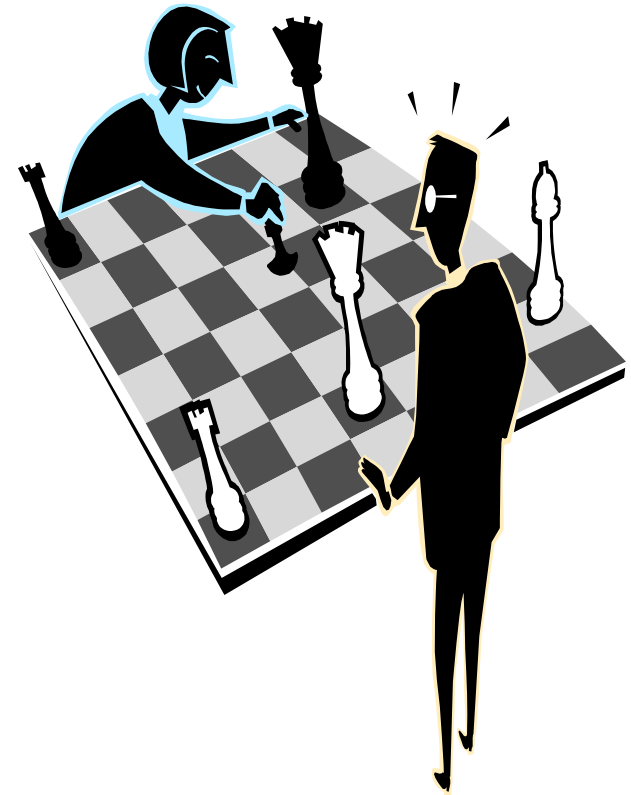
MTMP Tactical Requirements

- Pharmacists Can:
 - Electronically craft plans for each patient
 - Electronically monitor plan operation and compliance
 - Track time and resources used
 - Use standard CPT codes for tracking, billing & reporting

- Comply with HIPAA:
 - For security and reporting
 - For electronic medical records for pharmacology and plan implementation.
 - Automate administrative burden and minimize time spent

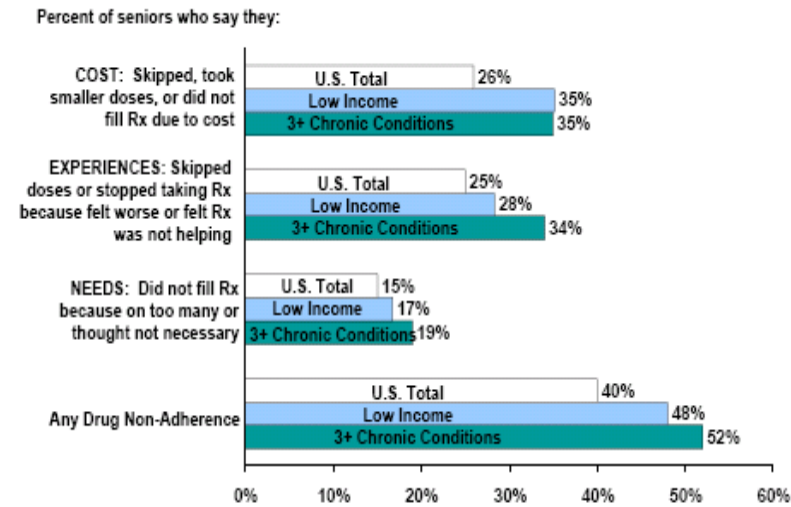
- Provide Accurate internal tracking
 - To support premium adjustments
 - Relate resources to fees charged
 - Justify payments to pharmacists for MTMP services
 - Justify all billing
 - Set/define/justify best practices by being the leader in this area

- Produce tailored electronic reports for all parties:
 - Patients
 - Pharmacists & providers
 - Administrator
 - Medicare
 - Drug Plans & Regulators
 - Other regulatory agencies as required (HIPAA, etc.)



The Need for MTMP - 1

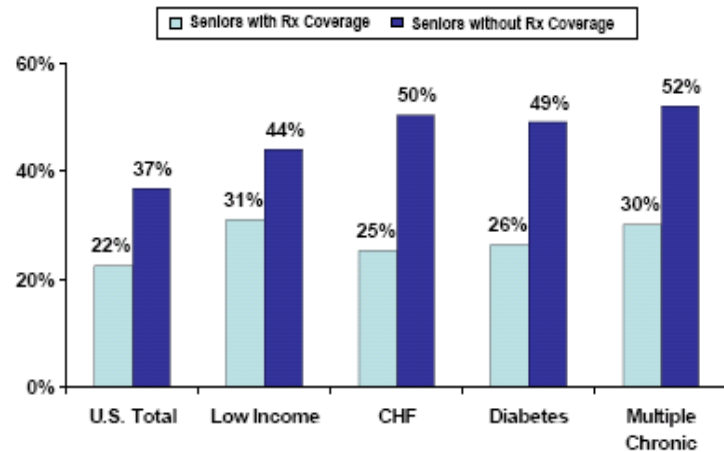
Figure 1
Two of five seniors report not taking medications as prescribed
 Poor experiences with drugs and costs contribute to non-adherence



Note: Rx = prescription medication. Low Income is 200 percent of the federal poverty or less.
 SOURCE: Kaiser/Commonwealth/Tufts-New England Medical Center 2003 National Survey of Seniors and Prescription Drugs.

Figure 3
Drug coverage matters: Seniors without drug coverage report higher rates of non-adherence than those with drug coverage

Percent of seniors not filling medications or skipping or taking smaller doses due to costs:



Note: Rx = prescription medication. Low Income is 200 percent of the federal poverty level or less.
 SOURCE: Kaiser/Commonwealth/Tufts-New England Medical Center 2003 National Survey of Seniors and Prescription Drugs.

- Risks of Non-Compliance with Prescribed Medication Therapy
 - Non-compliance can significantly reduce medications' beneficial effects.
 - Non-compliance can dramatically increase the possibility of adverse interactions (e.g., cortisone, etc.).
 - The costs of non-compliance far exceed the costs of compliance – (for everyone).
 - Other indications may arise that were previously unknown – or unanticipated.

The Need for MTMP - 2

- Demographics
 - Today there are 38 million seniors in the US; by 2030, that number will rise to 75 million.
 - Every day in the US, another 6,000 people turn 65.
 - There are 5.5 million seniors with long-term disabilities in the US. This figure is expected to increase to 10 million by 2020 and to 20 million by 2040.
 - Seniors' annual prescription drug expenditures are estimated at \$65 billion now (2005). Senior expenditures will be over \$110 billion by 2010.
- Risks of Ignoring MTMP
 - Number of drug interactions increase quadratically with the number of medications taken [Int. = $(n^2 - n + 1)$].
 - Number of possible adverse reactions increases quadratically also.

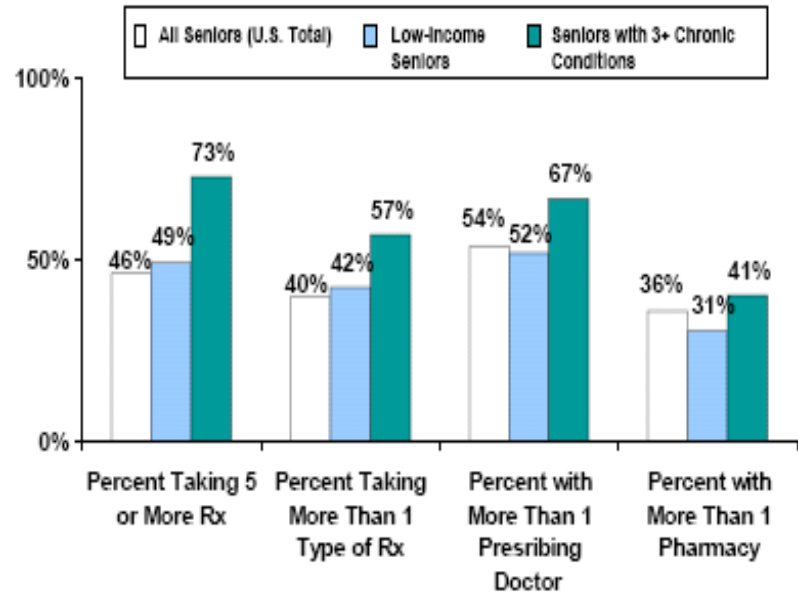
No. of Meds	No. of Interactions
1	1
4	13
7	43
10	91

Source; US Census Bureau; American Society of Consultant Pharmacists

Figure 2

Seniors – especially those with 3 or more chronic conditions – rely heavily on medications

Many have multiple prescribing doctors and use more than 1 pharmacy



Note: Rx = prescription medication. Low Income is 200 percent of the federal poverty level or less.
 SOURCE: Kaiser/Commonwealth/Tufts-New England Medical Center 2003 National Survey of Seniors and Prescription Drugs.

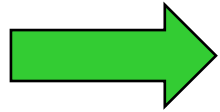
The Need for MTMP - 3

- **Estimated Annual Cost of Medication Related Problems**
 - \$76.6 billion among the ambulatory population
 - \$20 billion in acute-care facilities
 - \$7.6 billion in nursing facilities
 - Total annual direct medical cost of medication-related problems in the United v States: **\$104.2 billion**
- **Senior Care Pharmacy Facts:**
 - Adverse drug reactions are among top five greatest threats to health of seniors
 - 28% of hospitalizations among seniors are due to adverse drug reactions.
 - 32,000 seniors suffer hip fractures each year due to falls caused by medication-related problems.
 - The elderly account for 12.7% of the U.S. population, but consume approximately 34% of total prescriptions.
 - On average, individuals 65 to 69 years old take nearly 14 prescriptions per year, individuals aged 80 to 84 take an average of 18 prescriptions per year.

Source: American Society of Consultant Pharmacists

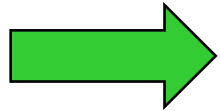
MTMP Benefits to Pharmacists

Opportunity



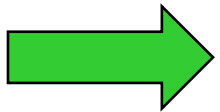
- Bill PDP for professional services
- Reimbursed at \$1 - \$3 per minute for professional services

Barrier



- Manual implementation very costly & error-prone; misuses time, staff, dollars.

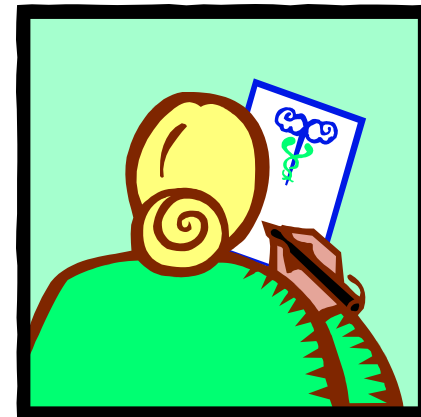
Solution



- Automate MTM activities to:
 - Easily document and verify all activities covered under Medicare Part D
 - Easily prove HIPAA compliance
 - Easily prove compliance to PDP to ensure payment
 - Easily provide an audit trail
 - Easily integrate to existing pharmacy systems (without outside help or new tech work)

MTMP Benefits to Member Service Providers

- Bill for MTM professional services
- 100% HIPAA-and Medicare-compliant with a comprehensive activity audit trail
- “Tax” the transaction for additional revenue
- Offer MTMP systems to member pharmacies to increase revenue
- Detect, identify and respond to trends
- Detect, identify and reduce fraud.
- Easily document & prove HIPAA and Medicare compliance



MTMP Benefits PDPs-1

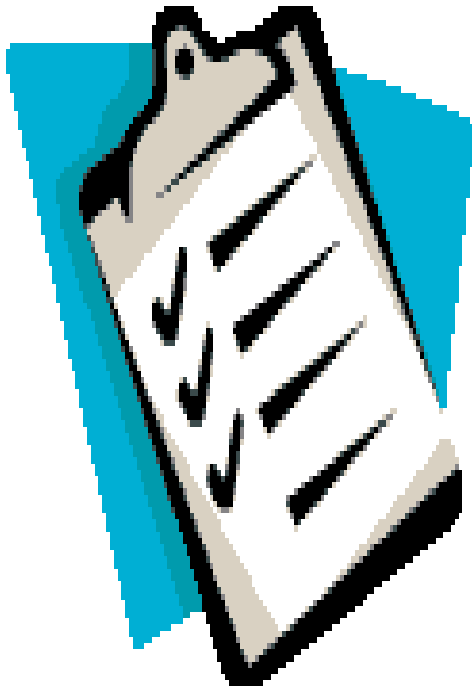
“Lack of patient compliance represents an enormous cost to our health care system, and a significant danger to patients. Nearly half of all refillable prescriptions are never refilled, and industry figures indicate that **10-15% of all hospital admissions are the result of improper use of medications**. One of APA's initial projects establishes a refill reminder program to help patients stay compliant in taking their medication, thereby receiving the full benefit intended. In addition, it provides an efficient means of channeling educational materials to defined groups of patients”

-American Pharmacy Alliance

- Reduces
 - Drug costs through error reduction
 - Claim filings
 - Legal expenses

- Enables Quick, Simple
 - Delivery of MTM Plans to the largest group of Beneficiaries possible
 - Proving compliance with government regulations
 - Adapting to changes in government regulations
 - Spotting of trends
 - Reducing fraud

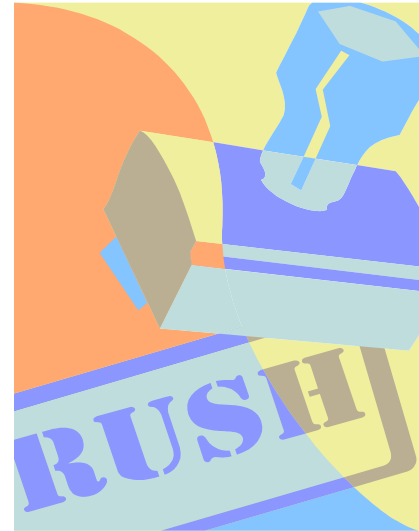
MTMP Benefits PDPs - 2



- Prove & maintain regulatory compliance
- Tamper-proof audit trail
- Report in verifiable way
- Implement easily & efficiently
- Work seamlessly with existing PDP IT systems

MTMP Benefits PDPs - 3

- Information collection
- Information sorting & dissemination
- Time tracking
- Report generation and routing
- Rule-based
- Interoperable
- Adapt to regulatory changes on-the-fly



MTMP Outputs/Reports - 1

- For Patients:
 - Drug prescription(s) and dosage(s).
 - Drug usage (over/under).
 - Indications and contra-indications.
 - Drug information & known interaction(s) data sheets.
 - Drug refills and reminders.
 - Pharmacist's comments and observations.
 - Physician's comments and observations.
 - MTM Plan description and adherence tracking.
 - TrOOP Reports (Tracking Out-of-Pocket expenses).



MTMP Outputs/Reports - 2

- For Pharmacists/Pharmacies:
 - Drug prescription(s), dosage(s), usage (over/under), refill reminders.
 - Generic versus total drugs prescribed.
 - Patient access – who, when how often, where, etc.
 - HL7 format for report output.
 - Patient plan compliance verification.
 - Pharmacist's & Physician's comments and observations.
 - Time spent per patient.
 - Time spent per condition.
 - Unusual activity alarms (per-patient, per condition, etc.).
 - Frequency distribution of conditions (cold/flu season, etc.).
 - Adverse event observation and tracking.



MTMP Outputs/Reports - 3

- For Administrators:
 - Pharmacy activity tracking in support of MTMPs.
 - Plan adherence tracking.
 - Time usage distribution.
 - HL7 reports with industry standard CPT codes generated automatically.
 - Fraud detection and unusual activity warnings.
 - HIPAA-compliance audit trail and verification.



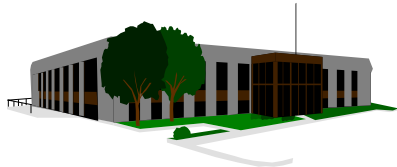
MTMP Outputs/Reports - 4

- For Drug Plans & Government Regulators:
 - Pharmacy activities related to MTMPs.
 - Pharmacist's time usage tracking.
 - Verification of pharmacist's billings.
 - Pharmacy tech(s)' time usage tracking.
 - HL7 Report format w/CPT codes.
 - Time and resource tracking.
 - Plan adherence tracking.
 - Fraud detection and unusual activity warnings.
 - HIPAA-compliance audit trail and verification.
 - Verification of efficiency and optimal plan management.



IQware MTMP System

**Administrator and/or
Drug Plan
Headquarters**



Reports (Outputs)

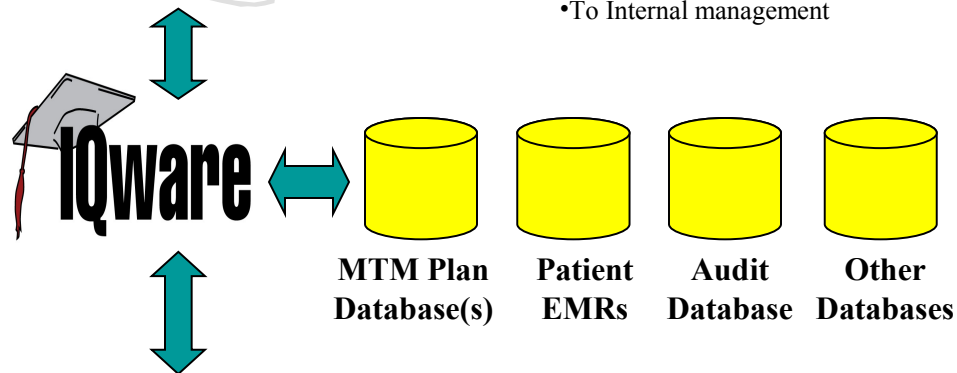
- To PDPs
- To regulatory authorities
- To pharmacies
- To Internal management

Key Advantages

- Secure & patent-pending
- HIPAA-Compliant
- Can track and control patient access and content delivery
- Physically secure – content is only displayed when authorized and requested
- Supports tailored content on a per-pharmacy basis
- Content's appearance can be altered at any time
- Content may be upgraded from anywhere.

Key Attributes

- Hacker-Proof & Secure
- HIPAA compliant audit trail
- Interoperable – use any client
- Can work with existing fulfillment systems



To Member Pharmacies

- Each pharmacy is configurable
- Full content control & tracking
- Full auditing, reporting & billing

 **IQware**

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Secure Pharmacist Console

- Hacker-Proof & Secure
- Private – pharmacist only
- Prepare plans and make available for patients
- Enter observations & comments
- View patient data and reports
- Update at any time



Secure Patient Access

- View MTM plan and progress
- See important reminders
- See drug information, interactions and warnings
- Ask questions/leave notes for pharmacist



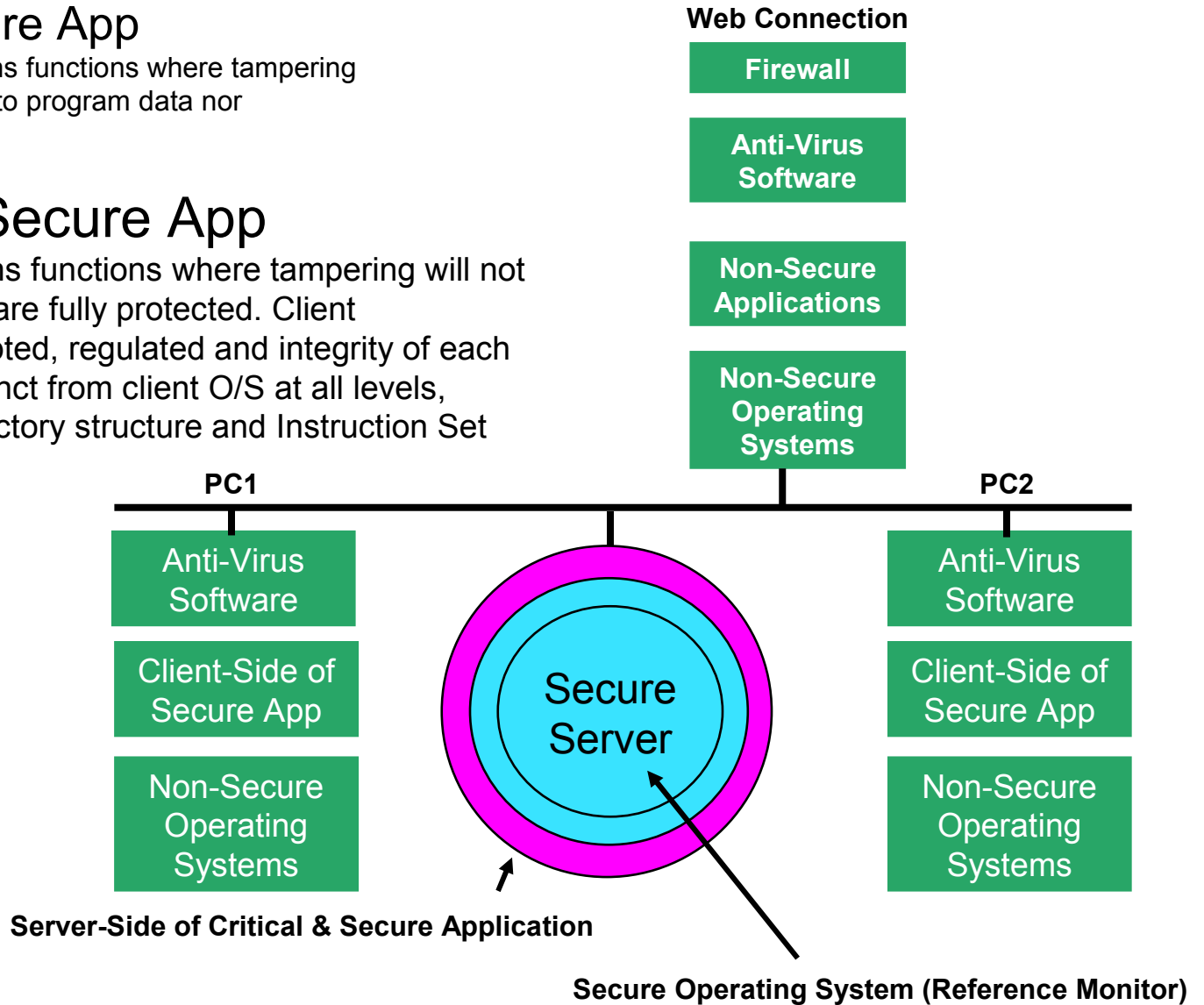
Secure Architecture

Client Side of Secure App

Performs non-critical applications functions where tampering may occur but is not damaging to program data nor program operation

Server Side of Secure App

Performs critical applications functions where tampering will not occur. Data and programs are fully protected. Client communications are encrypted, regulated and integrity of each transaction is verified. Distinct from client O/S at all levels, including file structure, directory structure and Instruction Set Architecture (ISA)



What Secure Systems Must Do

■ Policy

- **Security Policy** - System must enforce a well-defined security policy.
- **Marking** - System must associate all objects with access control labels (sensitivity & access modes).

■ Accountability

- **Identification** - System must identify individuals and their various authorizations in a secure manner.
- **Audit Trail** - System must keep & protect audit trail so actions may be traced to responsible party.

■ Assurance

- **Evaluation** - System must have hardware/software mechanisms that can be independently evaluated to assure that policy & accountability are enforced.
- **Continuous Protection** - System must continuously protect trusted mechanisms that enforce policy & accountability from tampering.



Secure System Classifications

■ DoD Rating System

- 7 levels of security.
- Grades are level D (lowest), C1, C2, B1, B2, B3, A1 (highest).
- Emphasis is on structure.
- All desktops in level D - too low to even bother rating.

■ NIST and NIAP Rating System

- 7 levels of security.
- Grades are EAL-1 (lowest) thru EAL-7 (highest).
- Emphasis is on external testing.
- Better definitions than DoD but not as rigorous.



(NIST - National Institute of Standards & Technology)
(NIAP - National Information Assurance Partnership)

ISO 15408

45CFR164 Security & Privacy

Functional Specifications

Ensure confidentiality of all electronic records
Protect against reasonably anticipated threats to hazards to security
Protect against reasonably anticipated uses or disclosures
Ensure compliance by workforce

Security approach may be flexible
Have to assess risks to security of information
Can take into account existing IT infrastructure
Implementation specifications may be required

Risk analysis is required - covering all potential vulnerabilities
Security management process is required - implement policies to prevent, detect, contain and correct security violations
Risk management is required - implement security procedures to reduce risk and vulnerabilities
Sanction policy is required - apply appropriate sanctions to workforce members who do not comply with procedures
Information system activity review is required - regular review of IT system activity via audit logs, security incident tracking, etc.

IQware Attributes

Meets requirements
Meets requirements
Meets requirements
Does not Address

Meets requirements
Service available
Meets requirements
Service available

Service available
Service available

Service available

Service available

Meets requirements

Implementation Specifications

Security Awareness Training

Security reminders and updates
Protection from malicious software
Log-in monitoring
Password management

Response and Reporting

Identify & respond to security incidents (known or suspected)
Mitigate harmful effects
Document the event and outcome

Meets requirements
Meets requirements
Meets requirements
Meets requirements

Meets requirements
Meets requirements
Document service available

45CFR164 Security & Privacy

Implementation Specifications

IQware Attributes

■ Contingency Plan

- Data backup plan
- Disaster recovery plan
- Emergency mode operation plan
- Testing and revision procedures
- Applications and data criticality analysis

“On-the-fly” Backup
Service available
Service available
Service available
Service available

■ Technical Safeguards

- Access control
- Unique user IDs
- Emergency access procedures
- Automatic logoff
- Encryption and decryption (addressable)
- Audit trail and controls
- Transmission security
Implement procedure to protect record from unauthorized access when transmitted over a network.
- Person or entity authentication
Verify that entity accessing record is the one claimed.
- Integrity
Implement policies & procedures to protect records from improper alteration or destruction.
- Authentication
Implement mechanism to authenticate records, Implement mechanism to corroborate that record has not been altered or destroyed in an unauthorized manner.

Service available
Enforced feature
Service available
Meets requirements
Available
Secure and complete
Yes, user selects

Yes, user implemented

Yes, user selects

Yes, user chooses