CMS-4119-P-64

Submitter : **Date: 12/15/2006**

Organization :

Category : **Association**

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-4119-P-64-Attach-1.PDF

Heart Disease and Stroke. You're the Cure.

American Heart Association® | American Stroke Association®
Learn and Live.™

December 15, 2006

Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-4119-P
PO Box 8017
Baltimore, MD 21244-8017

Re: CMS-4119-P

Dear Sir/Madam:

On behalf of the American Heart Association (AHA), including the American Stroke Association (ASA) and over 22.5 million AHA and ASA volunteers and supporters, we appreciate the opportunity to submit our comments in response to the Centers for Medicare and Medicaid Services (CMS) proposed rule to use Medicare Part D claims data for other research, analysis, reporting and public health functions.

Since 1924, the American Heart Association has dedicated itself to reducing disability and death from cardiovascular disease and stroke – the #1 and #3 leading causes of death in the United States – through research, education, community based programs and advocacy. AHA and ASA are committed to achieving a reduction in cardiovascular disease, stroke, and associated risk by 25 percent by 2010. The ability of our organization to accomplish this goal is dependent on a number of factors. Our evidence-based process, however, depends for its success on the availability of robust, accurate patient-centered data for research and analysis. With ready access to this type of information, we can help to identify the best methods to prevent, diagnose, treat, and rehabilitate patients at risk for or suffering from cardiovascular disease and stroke.

According to the proposed rule, CMS intends to make a new set of health care data – Medicare Part D prescription drug administrative data – available for a number of non-payment-related purposes, including research and analysis for broader health care issues. Under the Agency's proposal, CMS, as well as other government agencies and external researchers, would have access to this Part D claims data. The data could be used to evaluate the effects of the Part D program on health outcomes and costs, conduct demonstration projects, support research efforts, perform oversight activities,

American Heart Association Advocacy Department
1150 Connecticut Ave., NW, Suite 300, Washington, DC 20036
202-785-7900 . Fax 202-785-7950 . www.americanheart.org/yourethecure

monitor patterns of drug use, and identify potential drug risks. CMS is also considering using the data to develop personalized medication history records accessible by Medicare beneficiaries. The proposal also authorizes CMS to link this information to that contained in other databases pertinent to health care research.

AHA strongly supports the Agency's proposal. Medicare Part D data should be available for non-payment-related activities that can advance the public health. If adopted as proposed, the rule would allow CMS, which is currently restricted from using Part D data for non-payment-related activities, to make full use of these valuable data and provide other government agencies and external researchers with access to drug claims information which would otherwise be unavailable to them. Access to these data would facilitate research on a number of issues of interest to the Association, such as medication adherence and persistence, drug usage by beneficiaries with specific chronic conditions, risk factors for adverse events and contraindications, the effectiveness of different treatment modalities, quality of services, and health disparities.

Sharing Data with Entities Outside of CMS

It is our understanding that Medicare Part D data will be available to other government agencies and external researchers under the same protocols currently used to access Medicare Parts A and B data. Researchers would have to enter into a standard data use agreement and each request would be evaluated to determine whether the data request is related to a legitimate research purpose, only the minimum data required to conduct the study would be released, and that the confidentiality of beneficiary information is strictly protected.

AHA appreciates the value of uniformity in the data request system. Requiring researchers to use the same method to request all Medicare data may help to simplify the data request process. However, some researchers have reported difficulty accessing pertinent information from Medicare and other federal databases in the past. We are concerned that researchers attempting to use Medicare Part D data could experience similar problems. For example, databases housing Part D data are designed to allow for payment of plan sponsors, not to facilitate research. Therefore, the data included in the data sets may be deficient for certain research purposes or may be presented in a manner that is difficult to use effectively. AHA encourages CMS to consider how to make Part D data readily accessible and useful to outside entities. Clearly, this effort should not be limited to Part D data, but should be conducted as part of a larger effort to improve accessibility to federal databases for broad research purposes.

If the Agency moves forward in implementing this rule, CMS should also consider how to maximize the utility of the data. Specifically, AHA recommends that CMS ensure that Part D data is available in a clean, useful format. To facilitate the broader research purpose, data must be sufficiently detailed, yet secure. Data sets made available to researchers for analysis must include individual data for each beneficiary rather than data presented in the aggregate, but the data must be de-identified to protect individual beneficiary privacy. By including data on the individual level that can be linked to data from Medicare Parts A and B, researchers will be able to evaluate how the prescription drug benefit interacts with benefits provided under Medicare Parts A or B. To be of maximum value to the research community, data files should also include specific information on each beneficiary, including the beneficiary's age, primary diagnosis, and key co-morbidities, as well as information on the medications utilized, the

dosages of each medication, medication refill history, and medication cost. Information on the beneficiary's insurance coverage such as whether the individual is enrolled in a Part D prescription drug plan (PDP) or a Medicare Advantage prescription drug plan (MA-PD) and enrollment information in any medication therapy management program, if applicable, would also be of assistance.

In summary, AHA strongly supports CMS' proposal to make Medicare Part D claims data available to non-Agency researchers for broader analysis, reporting and public health functions. Part D prescription drug data – when combined with data from Medicare Parts A and B – will allow CMS, other federal agencies, and external researchers to examine a number of important public health issues affecting the elderly and disabled including cardiovascular disease and stroke. To maximize the utility of this data, we urge the Agency to provide detailed information on the individual beneficiary level, not aggregate information, and to ensure that data is released to outside entities in a clean and useful format.

If you have any questions or need any additional information, please do not hesitate to contact Susan Bishop, MA, Regulatory Relations Manager, at 202-785-7908 or via email at susan.k.bishop@heart.org.

Sincerely,

Sue A. Nelson

Sue Nelson
Vice President of Federal Advocacy
American Heart Association

cc: Kenneth Baker, MD, FAHA, Chair, AHA Research Committee
Eric Peterson, MD, MPH, FAHA, Chair, AHA Quality of Care and Outcomes Research Interdisciplinary Working Group

Submitter : Dr. Dennis Deapen **Date:** 12/15/2006

Organization : University of Southern California

Category : Academic

Issue Areas/Comments

Information to be Collected

Information to be Collected

I writc in support of CMS release of Medicare Part D data for research purposes. As the director of the population-based cancer registry for Los Angeles, I am able to provide high quality cancer-related data to investigators who perform a wide variety of research.

Often, the value of the cancer registry data is greatly enhanced by linkage with other high quality data. One of the most highly used such databases is the SEER-Medicare file to which we contribute our Los Angeles cancer data. Addition of the Part D data will further expand the research potential in many areas of importance to the American public including patterns of accessibility to medications and prescribing patterns to cancer patients as well as survivorship, complications and other outcomes. Analysis of costs and benefits will facilitate in controlling Medicare costs as the Medicare-eligible population increases.

Today s information technology tools allow efficient and rapid analyses of these large databases and will produce rapid public health benefits.

Submitter : **Dr. Kamyar Kalantar-Zadeh** **Date: 12/17/2006**

Organization : **Harbor - UCLA Medical Center**

Category : **Academic**

Issue Areas/Comments

Applicability

Applicability

Medicare Part D medication data

Beneficiary Access of Part D Data

Beneficiary Access of Part D Data

We would be very interested to examine outcomes and cost-effectiveness indices of medical treatment in individuals with chronic kidney disease (CKD) stages 3 to 5 not on dialysis, as well as dialysis patients, who receive prescribed medications for the secondary hyperparathyroidism (SHPT), e.g. vitamin D analogs, calcium sensor blockers, and for hyperphosphatemia, e.g. phosphorus binders, The Medicare Part D data will allow us to identify these individuals and design and conduct this and similar studies about CKD outcomes. As an example I am enclosing our recent analysis using medication database (vitamin D therapy) in a group of CKD patients (see attached ASN 2006 abstract).

Sincerely,
Kamyar Kalantar-Zadeh, MD PhD

GENERAL

GENERAL

See attachment

Information to be Collected

Information to be Collected

Data will be shared with other research centers

Limitations

Limitations

Important and clinically relevant outcome data and information pertaining to CKD and ESRD care can be generated. See the following presented abstract as an example:

,

EXAMINATION OF OUTCOMES AND COSTS OF CARE AMONG PATIENTS WITH CKD AND SHPT

Schumock G1, Marx SE2, Boccuzzi SJ3, Blount A3, Sterz R4, Melnick JZ2, Williams LA2, and Kalantar-Zadeh K5

1University of Illinois at Chicago, Chicago, IL, USA; 2Abbott Laboratories, Abbott Park, IL, USA; 3Pharmetrics, Inc., Watertown, MA, USA; 4Abbott GmbH & Co., Ludwigshafen, Germany, 5 Harbor-UCLA, Torrance, CA, USA

Introduction
Secondary hyperparathyroidism (SHPT) can lead to significant morbidity, mortality, and healthcare resource utilization in CKD Stage 5. The objective of this study was to determine if SHPT patients experience similar clinical and economic consequences to predialysis CKD patients.

Methods
66,644 adult CKD pre-dialysis patients with and without SHPT were evaluated during a 72-month period (January 1999 December 2004). This retrospective cohort study using a patient-centric claims database grouped patients into 1 of 3 cohorts based on diagnosis of SHPT or vitamin D (D) therapy. Annualized estimates of mean direct medical costs and utilization following index CKD diagnosis were compared.

Results
Descriptive analyses reveal post-index costs increased greatest for CKD w/ SHPT and least for CKD w/ D (figure); annualized hospitalizations were greatest for CKD w/ SHPT.

Generalized linear models, using gamma distribution and a log link function for CKD-related annualized costs, adjusted for potential confounders (gender, age, plan type, payer type, geographic region, physician specialty, pre-index co-morbidities, and pre-index total healthcare costs) revealed CKD w/ SHPT had 594% ($P < 0.0001$) higher costs compared to CKD w/o SHPT or D. CKD w/ D compared to CKD w/o SHPT or D demonstrated lower costs ($P < 0.05$).

Conclusion
Predialysis CKD patients with SHPT are associated with significantly greater direct costs and inpatient hospitalizations compared to predialysis CKD patients without SHPT. Treatment of SHPT in predialysis patients may lead to significant cost savings and reduced hospitalizations, as demonstrated in hemodialysis patients.

Purpose of CMS Collecting Information

Purpose of CMS Collecting Information

See enclosed abstract above. The USRDS data and other Medicare (CMS) data will be used and linked to Medicare data. Data from large dialysis organizations and centralized Health Care Providers such as Kaiser Permanente will be linked to these data.

Sharing Data with Entities Outside of CMS

Sharing Data with Entities Outside of CMS

The found association may not be causal. Some important variables such as comorbid states may not be optimally avialbale.

CMS-4119-P-66-Attach-1.DOC

----- Original Message -----
From: Kamyar Kalantar-Zadeh MD PhD
To: Eggers, Paul (NIH/NIDDK) [E]
Sent: Thursday, December 14, 2006 3:25 PM
Subject: Re: departure gift

Dear Dr. Eggers,

We would be very interested to examine outcomes and cost-effectiveness indices of medical treatment in individuals in CKD stages 3 to 5 not on dialysis, as well as dialysis patients, who receive prescribed medications for the secondary hyperparathyroidism (SHPT), e.g. vitamin D analogs, calcium sensor blockers, and for hyperphosphatemia, e.g. phosphorus binders, The Medicare Part D data will allow us to identify these individuals and design and conduct this and similar studies about CKD outcomes. As an example I am enclosing our recent analysis using medication database (vitamin D therapy) in a group of CKD patients (see attached ASN 2006 abstract).

Sincerely,
Kamyar Kalantar-Zadeh

EXAMINATION OF OUTCOMES AND COSTS OF CARE AMONG PATIENTS WITH CKD AND SHPT

Schumock G[1], Marx SE[2], Boccuzzi SJ[3], Blount A[3], Sterz R[4], Melnick JZ[2], Williams LA[2], Kalantar-Zadeh K[5]

[1]University of Illinois at Chicago, Chicago, IL, USA; [2]Abbott Laboratories, Abbott Park, IL, USA; [3]Pharmetrics, Inc., Watertown, MA, USA; [4]Abbott GmbH & Co., Ludwigshafen, Germany, [5] Harbor-UCLA, Torrance, CA, USA

Introduction

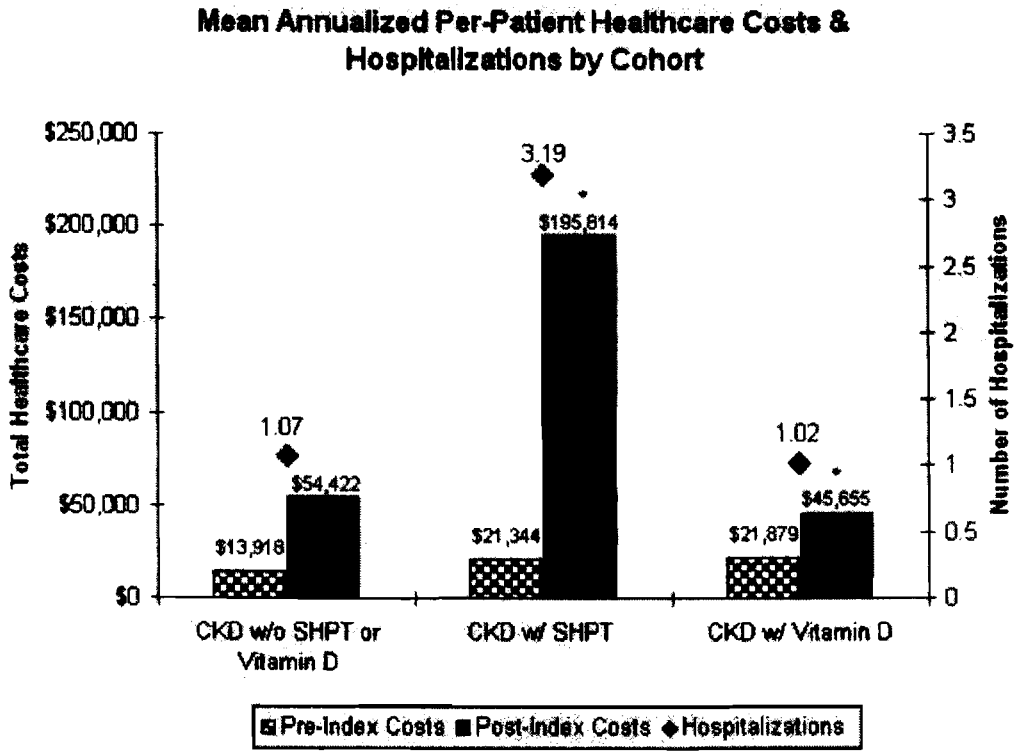
Secondary hyperparathyroidism (SHPT) can lead to significant morbidity, mortality, and healthcare resource utilization in CKD Stage 5. The objective of this study was to determine if SHPT patients experience similar clinical and economic consequences to predialysis CKD patients.

Methods

66,644 adult CKD pre-dialysis patients with and without SHPT were evaluated during a 72-month period (January 1999 – December 2004). This retrospective cohort study using a patient-centric claims database grouped patients into 1 of 3 cohorts based on diagnosis of SHPT or vitamin D (D) therapy. Annualized estimates of mean direct medical costs and utilization following index CKD diagnosis were compared.

Results

Descriptive analyses reveal post-index costs increased greatest for CKD w/ SHPT and least for CKD w/ D (figure); annualized hospitalizations were greatest for CKD w/ SHPT.



*P <0.0001; Differences between cohorts were analyzed using chi-square for categorical variables and Wilcoxon rank-sum tests for continuous variables with CKD w/o SHPT as a reference cohort.

Generalized linear models, using gamma distribution and a log link function for CKD-related annualized costs, adjusted for potential confounders (gender, age, plan type, payer type, geographic region, physician specialty, pre-index co-morbidities, and pre-index total healthcare costs) revealed CKD w/ SHPT had 594% (P <0.0001) higher costs compared to CKD w/o SHPT or D. CKD w/ D compared to CKD w/o SHPT or D demonstrated lower costs (P <0.05).

Conclusion

Predialysis CKD patients with SHPT are associated with significantly greater direct costs and inpatient hospitalizations compared to predialysis CKD patients without SHPT. Treatment of SHPT in predialysis patients may lead to significant cost savings and reduced hospitalizations, as demonstrated in hemodialysis patients.

Submitter : Harvey Ashman **Date:** 12/18/2006

Organization : IMS Health Incorporated

Category : Health Care Industry

Issue Areas/Comments

Applicability

Applicability

See Attachment

Beneficiary Access of Part D Data

Beneficiary Access of Part D Data

See Attachment

GENERAL

GENERAL

See Attachment

Information to be Collected

Information to be Collected

See Attachment

Limitations

Limitations

See Attachment

Purpose of CMS Collecting Information

Purpose of CMS Collecting Information

See Attachment

Sharing Data with Entities Outside of CMS

Sharing Data with Entities Outside of CMS

See Attachment

CMS-4119-P-67-Attach-1.PDF

ims

Harvey A. Ashman
Vice President, Law - Americas Region

IMS Health Incorporated
660 West Germantown Pike
Plymouth Meeting, PA 19462
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hashman@imsamericas.com

December 17, 2006

Ms. Leslie Norwalk
Acting Administration
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-4119-P
P.O. Box 8017
Baltimore, MD 21244-8017

Subject: Comments on Proposed Rule – CMS-4119-P

Dear Ms. Norwalk:

IMS Health Incorporated ("IMS") appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services ("CMS") proposed rule to allow the Secretary to use claims information collected for Part D payment purposes for other research, analysis, reporting, and public health functions as published in the Federal Register on Wednesday, October 18, 2006.

IMS is the world's leading provider of health information intelligence for the healthcare industries. Headquartered in Fairfield, Connecticut, IMS has over 50 years experience achieving interoperability across health care data, with vast experience in the collection and analysis of pharmaceutical and medical claims data. As a company that collects and bridges pharmaceutical data sourced from more than 225,000 different supplier sites and medical and pharmaceutical claims for over 45 million patients, we know the value of claims data to research and analysis of every sector of our healthcare system. In the United States alone, IMS processes hundreds of million of patient de-identified healthcare records monthly, receiving data from pharmacies, pharmaceutical wholesalers, manufacturers, hospitals, clinics, physicians, health plans and others. The analytics and services we provide supports many types of research, including studies of: health outcomes, disease prevalence, burden of illness, pharmacoepidemiology, pharmaco-vigilance, drug utilization, health economic and resource utilization, provider practice patterns and patient compliance assessment, and quality of care evaluation.

The attached specific comments on the proposed rule are based on our 50+ years of experience collecting, integrating, and establishing extensive pharmaceutical and medical claims databases. We would like to highlight these issues:

- The free flow of data is vital to patient safety, quality promotion, price transparency, and program integrity. CMS correctly and clearly identifies the key goal and rationale for collection of Part D data, which is to promote the data flow to advance these public goals. (Purpose of CMS Collecting Information)

- Prescriber identity is a fundamental and needed data element to analysis and data flow that advances patient safety, quality of care and program integrity. CMS correctly identifies this data element as essential to the data base. (Information to be collected)

- We strongly encourage CMS to permit broader access to Part D data (with appropriate privacy and confidentiality safeguards), permitting commercial access to such data would allow innovative and essential information analysis to advance patient safety, health oversight, and oversight by entities such as disease management companies, managed care organizations, and other commercial organizations engaged in health information transparency functions. Properly protected commercial access has the potential to add a dimension of analysis that cannot be accomplished by the government or research community and will shed insights leading to enhanced public safety, quality of care and cost savings. (Sharing Data with Entities Outside of CMS)

IMS specific comments follow, and are organized by issue section as directed by the CMS Proposed Rule. We thank you for this opportunity to comment on the proposed rule.

Respectfully submitted,

Harvey A. Ashman

Harvey A. Ashman
Vice President, Law - Americas Region
IMS Health Incorporated

Cc: Secretary Leavitt
Attachment

ATTACHMENT

IMS Health Incorporated
Specific Comments on
Proposed Rule – CMS4119-P

"Purpose of CMS Collecting Information":
IMS Supports CMS' Goal and Rationale for the Collection of Part D Data

IMS agrees that the Secretary possesses the statutory authority to use Part D claims data for purposes other than payment. The proposed rule correctly states that the Social Security Act grants the Secretary of Health and Human Services the authority to include language in Part D contracts requiring the organization to provide the Secretary "with such information...as the Secretary may find necessary and appropriate." Section 1860D-12(b)(3)(D). Likewise, IMS agrees with CMS' rationale for expanding the use of the data beyond payment purposes. As CMS recognizes, the Part D claims data provide critical and otherwise unavailable sources of information for evaluating the efficiency of the new prescription drug benefit, reporting to Congress and the public on the financial expenditures and other pertinent statistics on the Medicare Drug benefit, including its effectiveness and impact on health outcomes.

IMS also agrees with CMS that the utilization of these data, and fostering the free flow thereof, is vital to achieving the broad goals of improving the health of Part D beneficiaries, and ensuring the efficient and cost-effective operation of the Part D program. As CMS recognizes, accurate assessment of the performance of the Part D prescription drug benefit will require a detailed assessment of the program at a macro-, and micro-level. Individual prescription drug transactions, as well as local, regional, and national trends within the program must be analyzed to ensure best outcomes for beneficiaries and the program. Thorough and detailed data about the Part D program is essential to conducting these analyses. Likewise, the free exchange of the data between CMS and providers is needed to assure that programmatic improvement impact individual beneficiaries.

It is also the view of IMS that Part D claims data, in addition to enhancing Part D performance, have utility in other important health care objectives.

"Information to be Collected":
IMS Supports CMS' List of Essential Data Elements, Including Prescriber Identity

In the proposed rule, CMS comments that the claims data for 2006 includes 37 data elements. In addition, reference is made to the "Prescription Drug Event data instructions" for a full description of the information contained in the data elements. Two of the key elements are: "*Identification of the pharmacy* where the prescription was filled" and "*Identification of the prescribing health professional* (emphasis added)." IMS strongly supports the inclusion of both pharmacy and prescriber identifiable information in the Part D data collected by CMS. These data are needed to assess the positive and negative health outcomes in Part D beneficiaries, to monitor the efficiency of Part D program operations, and for program integrity and other

program operation purposes. In particular, prescriber identity will be an essential element for analytic work requiring projections, forecasting, or which requires accurate targeting of educational materials to promote patient safety while simultaneously maintaining important patient privacy safeguards. Similarly, provider identity may be utilized in conjunction with programs intended to accelerate quality improvement or adoption of best practices (disease or care management). The fundamental statistical analytics of imputation, forecasting, and accurate aggregation require prescriber identity in the underlying data.

A specific example, recently detailed by the Department of Justice, Drug Enforcement Agency (DEA) in the 10/19/2006 Federal Register (pages 61801 – 61803), describes the "Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2007". Using an IMS Health Government Solutions estimation methodology to develop robust projections of medical needs for ephedrine and pseudophedrine, the DEA is able to establish production and import quotas for legitimate medical use and deter illicit use. Data containing provider identity was an essential input to this methodology.

Appropriate Use Standards for Physician Identifiable Part D Data

The collection and use of de-identified (patient anonymized) Part D claims data for purposes other than payment contains no threats to privacy. Among public and private healthcare experts, there is no debate that the privacy of Medicare beneficiaries personal information collected in claims data, or through other means, must remain private. In several states, physicians have asserted a claim to professional privacy and attempted to gain such rights. IMS strongly believes that physicians, pharmacists, and other healthcare providers do not have a privacy right to transactions made in the course of providing health care services, including any information contained in a Part D claim. The provision of a right to privacy for professionals in conduct of work for which they were publicly licensed to conduct would interfere with important public health and policy goals/functions. To meet concerns about inappropriate use, we recommend establishment of a standard for disclosure of physician identity to any entity in receipt of such information. An example of such a standard may be found in the bill recently introduced by Senators Grassley and Baucus, S.3897, the "Medicare Data Access and Research Act," Sec. 1121B(f)(B), which states in pertinent part:

> CONFIDENTIALITY OF PHYSICIANS AND MEDICAL PRACTICES- The safeguards established under subparagraph (A) shall ensure that the data provided to a research center or organization under this section that identifies individual physicians or medical practices is not released by the research center or organization, or otherwise made public.

We recommend that this language be added to the rule to encourage proper use and standards on provider identifiable data and to provide guidance on appropriate use of this data which do have some level of sensitivity.

Sharing Data with Entities Outside of CMS:
IMS Supports Use of Part D Claims Data Beyond the Uses in CMS' Proposed Rule

IMS believes in the efficacy of utilizing robust Part D claims data to advance positive health outcomes and strongly urges CMS to consider the use of such data beyond the purposes stated in the rule. Private companies (commercial entities) such as managed care companies, disease management organizations, health plans, pharmacy benefit managers, and health technology companies use health data to promote better health and product safety. Such work is essential to promoting transparency and innovative analysis of information to empower consumers, yet the restrictive approach proposed by CMS would unduly limit this potential and run counter to the transparency objectives broadly embraced. Part D claims data provide a valuable asset to further work on such objectives as drug safety, increasing transparency and limiting the incidence of fraud in the Part D program, regardless of the type of entity – university, non-profit or for-profit – that uses the data.

CMS also has a history of using data to promote transparency in the Medicare Part D program and advance the transparency priority articulated in President Bush's August 22, 2006 Executive Order. Through data submitted and sophisticated web-access tools, CMS has implemented a plan finder tool for Medicare beneficiaries. Part D claims data may, in fact, provide important information to add to or supplement such important steps forward on transparency. For example, such data could be vital to development of a Part D plan quality report card system.

CMS key concern should focus not on the type of entity that may be seeking access to the data, but rather whether (1) such access serves to level-fit the public, and (2) such access will not result in the public release of private or confidential information. Further, the size of the Medicare population is so large that it needs to be available to the rest of the population (represented by commercial entities) in order to understand overall treatment patterns and dynamics, drug interactions, risks in complex treatment regimens (abundant among this population), best practices, etc. Commercial entities need longitudinal, de-identified data to monitor risk, treatment gaps, outcomes and outcomes management/population management, and compare them to other populations. Further, this information is needed on a timely basis, requiring an investment in staff and assets not common among Government agencies. It is likely that commercial entities can fill the gap between what is needed and what is available.

Submitter : Dr. Simon Cohn **Date:** 12/18/2006

Organization : National Committee on Vital and Health Statistics

Category : Federal Government

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-4119-P-69-Attach-1.WPD

The proposed rule is broadly consistent with NCVHS' view that public benefits can be enhanced though the sharing of data both across government agencies and with responsible and qualified research organizations. The proposed rule also recognizes the essential need for appropriate levels of protection of individual beneficiary privacy though the restriction of data releases to the minimum elements necessary for the conduct of the study and subject to the existing mechanisms for data use agreements. At the individual level, the rule also reflects the increased demand of the public for access to its own records for such purposes as the creation of personal (typically electronic) health records.

In sum, the NCVHS wishes to reinforce that substantial public benefit can be derived through efforts to make the best use—including sharing of claims information and ancillary data—of information collected under Medicare Part D program. NCVHS recommends that the Department issue as expeditiously as possible a final rule that is fully supportive of the goals and the mechanisms to pursue them specified in the draft rule.

Sincerely,

S D. Cohn MD

Simon Cohn, M.D., M.P.H.
Chairman, National Committee on Vital
and Health Statistics

Cc: HHS Data Council Co-chairs
Director, Centers for Medicare and Medicaid Services (CMS)

Submitter : Mr. David St. Clair **Date:** 12/18/2006

Organization : MEDecision

Category : Health Care Industry

Issue Areas/Comments

Applicability

Applicability

See Attachment.

Beneficiary Access of Part D Data

Beneficiary Access of Part D Data

See Attachment.

GENERAL

GENERAL

See Attachment.

Information to be Collected

Information to be Collected

See Attachment.

Limitations

Limitations

See Attachment.

Purpose of CMS Collecting Information

Purpose of CMS Collecting Information

See Attachment.

Sharing Data with Entities Outside of CMS

Sharing Data with Entities Outside of CMS

See Attachment.

CMS-4119-P-70-Attach-1.DOC

CMS-4119-P-70-Attach-2.DOC

CMS-4119-P-70-Attach-3.DOC

CMS-4119-P-70-Attach-4.DOC

BLANK ROME LLP
COUNSELORS AT LAW

Phone: (215) 569-5724
Fax: (215) 832-5724
Email: burde@blankrome.com

December 18, 2006

Leslie V. Norwalk, Esquire
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-4119-P
P.O. Box 8017
Baltimore, MD 21244-8017

Re: CMS-4119-P

Dear Ms. Norwalk:

We represent MEDecision, a Pennsylvania company that provides software, services and clinical content to healthcare payors that allows such payors to improve the quality and affordability of healthcare provided to their members and to increase their administrative efficiency. MEDecision is responding to the proposed rule regarding the use of Medicare Part D data.

As an initial matter, MEDecision applauds CMS's recognition of the utility of Part D prescription drug event payment data ("Part D Claims Data") for a number of purposes. Our comments will respond not only to the proposed regulation, but also to CMS's ability to utilize claims data, not only from Part D, but also from Parts A, B and C of the Medicare program to improve the healthcare of each individual Medicare beneficiary.

Information to be Collected

MEDecision recognizes the import of collecting Part D Claims Data. We note that § 1860D-12(b)(3)(D) of the Social Security Act (42 U.S.C. § 1395N-112(b)(3)(D)) permits CMS to collect claims data from Part D sponsors. As important to the ultimate provision of care is the utilization of acute and ambulatory care claims data which might be collected under Parts A, B and C of the Medicare program. The statutory provision relied on by CMS regarding Part D Claims Data references the statutory provision on contracting for the Medicare Advantage Program, the "contract shall contain such other terms and conditions not inconsistent with this part as the secretary may find necessary and appropriate." (42 U.S.C. § 1395W-27(e)(1)). Therefore, the statute that CMS is relying upon 42 C.F.R. § 1395W-112(b)(3)(D) (Social Security Act § 1860D-

12(b)(3)(D)) equally supports the use of the Medicare Advantage Claims Data to support the proposed use of Part D Claims Data. If CMS has the authority to utilize Part D claims data under the cited provision of the Act, it likewise has the authority to utilize claims data under Part C as well.

We strongly urge CMS to make use of this rich source of claims information in order to improve the quality of care and services received by all Medicare beneficiaries.

Purpose of CMS Collecting Information

The statutory provision cited by CMS in support of the utilization of Part D Claims Data contains no language limiting the utilization of such data by CMS for purposes directly in support of improving the healthcare provided to Medicare beneficiaries.

While MEDecision strongly supports the proposed utilization of collected data for demonstration projects and would be pleased to participate in such projects, we believe the data on the improvement of patient care and the reduction of cost already exists to support the use of claims data from Part C and Part D. We have attached a recent study by the independent organization, HealthCore, which specifically addresses the strong economic case for the use of appropriately collected, integrated and clinically validated claims data in a payer-based health record at the point of care.

It should also be noted that with respect to a range of populations, Blue Cross/Blue Shield of Delaware, Blue Cross/Blue Shield of Illinois and Keystone Mercy Health Plan in the Greater Philadelphia area, are already using MEDecision's Patient Clinical Summary,[1] a claims-based health record, to improve the information available to providers at the point of care. Given the statutory authority relied upon by CMS under this proposed regulation, there is no reason why CMS cannot extend the proposal to include Medicare Advantage data as well.

Sharing Data with Entities Outside of CMS

Under proposed regulation at § 42 C.F.R. § 423.505(f)(5), CMS proposes to clarify its authority to share collected information with entities outside of government in accordance with applicable federal law. Again, pursuant to cited statutory authority and the proposed regulation, the logical extension would be to authorize the use of all Medicare claims data in a format useful for the provision of care by providers at the point of care. Indeed, we suggest clarifying the language under

[1] A copy of the MEDecision Patient Clinical Summary is attached. Please note that while the information is from a real patient, the record has been thoroughly deidentified per HIPAA standards.

proposed regulation at 42 C.F.R. § 423.505(f)(3)(iv) to specifically authorize demonstration projects and evaluations of using Medicare claims data in health records at the point of care.

Beneficiary Access to Part D Data

Pursuant to the foregoing citations, MEDecision strongly supports the use of Medicare claims data in a payor-based health record available to treating physicians pursuant to and compliant with the Health Insurance Portability and Accountability Act and implementing regulations. Consistent with the President's Executive Order 13335, authorizing the development of personal health records for every American, it is entirely consistent to use Medicare claims data to provide the basis for populating personal health records for Medicare beneficiaries. It is a matter of no dispute that Medicare beneficiaries due to age and infirmity receive more care from a broader range of providers and use more prescription drugs for a variety of ailments than any other segment of the population. Given the age and infirmity of most Medicare beneficiaries, it is difficult for them, as it would be for any person with multiple health issues, to accurately maintain a record of all of their respective diagnoses, treatments and prescriptions. A personal health record populated with Medicare claims data would greatly assist Medicare beneficiaries in planning and being compliant with their own care regimens.

Conclusion

CMS either has or has access to the richest source of information about each Medicare beneficiary. Unfortunately, to date, that information has not been utilized to improve the care provided to individual Medicare beneficiaries at the point of care. MEDecision looks forward to working with CMS to help develop the use of Medicare claims data in payor-based health records, whether provided directly to providers or in Medicare personal health records, or both.

Respectfully submitted,

Howard A. Burde

HAB/lln

Attachment

cc: David St. Clair
John Capobianco

MEDecision®
Collaborative Care Management

PRESENTS THE

PATIENT CLINICAL SUMMARY

(PATENT PENDING)

Report generated on: 03/15/2006 Information provided by: MCO 1
Report based on services provided as of: 02/28/2006

MEDecision

Patient Summary

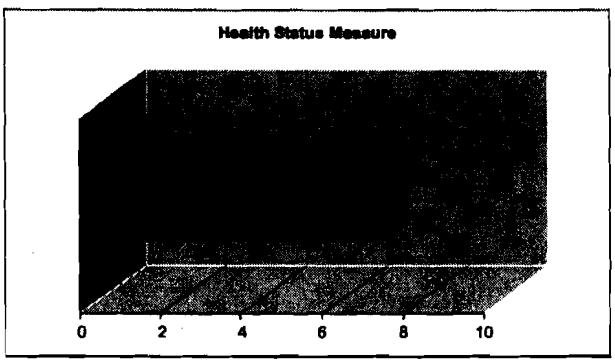
Name:	SMITH, JOHN	**ID:** JM1QBZJ1H00		**Eligibility:**	01/01/2000 - 12/31/2006
Address:	548 WEADLEY ROAD GULPH MILLS, PA 19406	**DOB:** 01/01/1956		**Phone (H):**	610-555-1212
		Gender: M		**Phone (W):**	610-555-1212
PCP:	STELLA, BRIAN	**PCP ID:** 610687090		**PCP phone:**	215-555-1212

Program and Severity

Program	Severity	Start/Update
DIABETES	High	11/01/2005
CONGESTIVE HEART FAILURE	Medium	01/01/2006

Health Status Measure

The Health Status Measure indicates risk in the next 12 months. 1 is low 10 is high.



Report generated on: 03/31/2006
Information provided by: MCO 1
Report based on services provided as of: 02/28/2006
Name: SMITH, JOHN
DOB: 01/01/1956

ID: JM1QBZJ1H00
Gender: M

Eligibility: 01/01/2000 - 12/31/2006

Medical Conditions

High Severity

Condition
DIABETES MELLITUS

Medium Severity

Condition
ULCERATIVE COLITIS
ISCHEMIC HEART DISEASE/ANGINA PECTORIS
HEART FAILURE (CHF)

Low Severity

Condition
NEUROMUSCULAR DISORDER

Inpatient Facility Admissions

Facility	Admit date	Disch. date	Days	Principal DX
KENTON LAFORGE	02/22/2005	03/02/2005	9	250.12 - DIABETES W/KETOACIDOSIS, TYPE II

Emergency Room Visits

PATIENT HAS HAD 0 EMERGENCY ROOM VISITS IN THE PAST 12 MONTHS

Report generated on: 03/31/2006
Information provided by: MCO 1
Report based on services provided as of: 02/28/2006
Name: SMITH, JOHN
DOB: 01/01/1956

ID: JM1QBZJ1H00
Gender: M

Eligibility: 01/01/2000 - 12/31/2006

Monitored Services

Service	# of services	Last service date	Most recent servicing provider	Phone #
HEMOGLOBIN A1C	3	07/31/2005	BRIAN STELLA	215-555-1212
GLUCOSE TESTING, BLOOD	5	07/31/2005	BRIAN STELLA	215-555-1212
CHEM./METABOLIC PANEL TESTING	5	07/25/2005	DIANA GUSSMAN	215-555-1212
CARDIAC MONITORING (HOLTER)	1	06/20/2005	WENDELL VENDETTI	215-555-1212
SURGICAL PATHOLOGY	1	04/30/2005	DIANA GUSSMAN	215-555-1212
ABDOMINAL ULTRASOUND EXAMS	2	04/17/2005	HEATH SUDDUTH	215-555-1212
URINALYSIS	4	04/16/2005	DIANA GUSSMAN	215-555-1212
AMYLASE (SERUM) ASSAY	2	04/16/2005	DIANA GUSSMAN	215-555-1212
CBC AND COMPONENT COUNTS	4	04/16/2005	DIANA GUSSMAN	215-555-1212
ELECTROCARDIOGRAM (ECG)	1	04/05/2005	WENDELL VENDETTI	215-555-1212
HEART ECHO EXAM	3	03/01/2005	WENDELL VENDETTI	215-555-1212
CALCIUM ASSAY	4	02/23/2005	DIANA GUSSMAN	215-555-1212
CARDIOVASCULAR STRESS TEST	2	02/22/2005	WENDELL VENDETTI	215-555-1212

Medications

Medication class	# fills	Last fill date
CARVEDILOL/COREG	9	12/28/2005
ACE INHIBITORS	9	12/28/2005
LANSOPRAZOLE/PREVACID	7	12/10/2005
AMOXICILLIN PREPARATIONS	1	04/29/2005
OSMOTIC LAXATIVE/BOWEL PREPS	1	04/17/2005
LOOP DIURETICS	3	04/13/2005
INSULIN	2	03 /26/2005
NEEDLES & SYRINGES	12	03/09/2005
AMOX K CLAVULANATE/AUGMENTIN	1	03/02/2005
AMLODIPINE/NORVASC	1	01/25/2005

Report generated on: 03/31/2006
Information provided by: MCO 1
Report based on services provided as of: 02/28/2006
Name: SMITH, JOHN
DOB: 01/01/1956

ID: JM1QBZJ1H00
Gender: M

Eligibility: 01/01/2000 - 12/31/2006

Providers Seen

Provider name	Specialty	Phone #	Last service date
WENDELL VENDETTI	CARDIOLOGY	215-555-1212	09/06/2005
BRIAN STELLA	FAMILY PRACTICE	215-555-1212	07/31/2005
LAWRENCE URBINA	EMERGENCY MEDICINE	215-555-1212	04/17/2005
KASEY CLONINGER	INTERNAL MEDICINE	215-555-1212	04/01/2005
DIANA GUSSMAN	ENDOCRINOLOGIST	215-555-1212	02/22/2005

Clinical Flags

Treatment Opportunities

- Diabetes and no Eye Exam in the past 12 Months
- Diabetic age 40 or older not on statin medication

Preventative Health and Wellness

- Age 50 to 52 and no colonoscopy in the past 2 years
- No blood test for cholesterol in the past 2 years

Active Care Management Summary

Problem: Testing frequency may be inconsistent with guidelines for A1C

Open: 11/02/2005	DM – Diabetes	Case ID: 1234567-0001

Goal(s):

- Member will seek A1C testing every 3-6 months.
- Member will demonstrate understanding of importance of A1C testing in monitoring diabetes care.

Problem: Overweight/Obesity with diabetes

Open: 01/10/2006	DM – Diabetes	Case ID: 1234567-0001

Goal(s):

- Member will demonstrate understanding of risk factors for condition/behavior.
- Member will set first weight loss goal at 10% of body weight.
- Member will increase physical activity to increase daily calorie deficit.

Closed Care Management Summary

Problem: Current Tobacco User

Open: 11/02/2005	DM – Diabetes	Case ID: 1234567-0001
Closed: 01/10/2006		

Goal(s):

- Member will seek assistance of support group.
- Member will demonstrate understanding of the treatment options that are available to help them.
- Member will make incremental and consistent changes to reduce health risk.

Information provided by: MCO 1

MEDecision

PATIENT CLINICAL SUMMARY

TERMS AND CONDITIONS FOR SECURITY AND CONFIDENTIALITY OF PATIENT RECORDS AND INFORMATION

1. General. An authorized provider ("Provider" or "You") are permitted to access certain patient care information for patients whom Provider treats in connection with Payor's care management program. Payor maintains confidential patient records and information that can be accessed through the Patient Clinical Summary software tools ("PCS System"). The PCS System is licensed to Payor by MEDecision, Inc. ("MEDecision") pursuant to a licensing agreement ("License Agreement"). MEDecision shall have the same rights against any Provider using the PCS System as it has against Payor under the License Agreement. Provider is placed in a unique position of trust since a major responsibility of Provider is the security and confidentiality of patient records and information. Security and confidentiality concern all providers who have access to confidential patient information. The purpose of these terms and conditions ("Terms and Conditions") is to clarify the Provider's responsibilities when utilizing the PCS System in connection with Payor's care management program. By accessing and utilizing this information, you agree to the Terms and Conditions of this agreement ("Agreement"). If you do not agree with these Terms and Conditions or you have inadvertently accessed this information, you should immediately cease using this information.

2. Scope of Use. Subject to the terms of this Agreement and for the sole purpose of assisting in the evaluation and treatment of patients, Provider is permitted to access and use the PCS System. Provider may use the PCS System and Confidential Patient Information (defined below) made available thereunder only upon patient consent and as authorized or required by applicable federal and state law, including, without limitation, the privacy and security regulations promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). You should refer to Payor's Privacy Policy for limitations on your right to use and disclose Confidential Patient Information in connection with Payor's care management program and to determine if a use or disclosure of such Confidential Health Information is otherwise permitted hereunder. You agree you have read and understand Payor's Privacy Policy. Use of Confidential Patient Information is permitted only for Provider's internal use on the PCS System in the ordinary course of business in connection with Payor's care management program, and such Confidential Patient Information shall not be used directly or indirectly on behalf of any other party. Further, notwithstanding anything to the contrary in these Terms and Conditions, Provider may not (a) use or otherwise disclose Confidential Patient Information for any other purpose other than a purpose expressly stated in these Terms and Conditions; or (b) use or disclose Confidential Patient Information in the manner that violates or would violate applicable federal or state law. Within these parameters, Providers may use Confidential Patient Information for, in, and on a single computer unit used by Provider (the "Work Station").

3. Security Key. Provider may activate and use the PCS System provided that Provider is a participating provider of Payor and has been issued an appropriate access code and password. Provider shall keep such access code and password secure from unauthorized access by and disclosure to any third party.

4. Confidentiality. In general, Provider must treat all patient records, materials, information and Protected Health Information ("PHI") accessed on or through the PCS System as confidential (collectively, "Confidential Patient Information"), and not use or disclose such Confidential Patient Information except as permitted hereunder. PHI means individually identifiable health information that is transmitted electronically or maintained in electronic or other medium. The term "individually identifiable health information" means health information, including demographic information collected from an individual that: (i) is created or received by a health care provider, health plan, employer or health care clearinghouse; and (ii) relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present or future payment for the provision of health care to an individual; and (a) identifies the individual; or (b) creates a reasonable basis to believe the information can be used to identify the individual. The term "health information" means any form of oral or written information that: (i) is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and (ii) relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual. Provider shall not, for any reason, either directly or indirectly, divulge any Confidential Patient Information to any third party or use such Confidential Patient Information for Provider's own benefit.

5. Expressly Prohibited Uses. Provider agrees that Provider (a) shall not make or permit unauthorized use or disclosure of any Confidential Patient Information maintained or stored on the PCS System or accessed by Provider through the PCS System; (b) shall not seek personal benefit or allow others to benefit personally by knowledge of any Confidential Patient Information which has come to him by virtue of his access to the PCS System; (c) shall not exhibit or divulge the contents of any record or report a false, inaccurate, or misleading entry; nor shall Provider knowingly expunge or cause to be expunged in any record or report a data entry; (d) shall not remove any official record or report or copy thereof from where it is maintained; (e) shall not aid, abet nor act in conspiracy with another to violate any part of these Terms and Conditions; (f) make unauthorized use or disclosure of the Confidential Patient Information; (g) disassemble, decompile, recast, or reverse engineer the PCS System or create a substantially

similar system; (h) distribute any Confidential Patient Information for commercial gain or otherwise; (e) copy the Confidential Patient Information in any form except as necessary to use such Confidential Patient Information in accordance with this Agreement; or (f) modify, alter, delete or obscure any Confidential Patient Information. Provider shall ensure his compliance with this Agreement and shall bear the responsibility for any breach of this Agreement by him. Any knowledge of a violation of these Terms and Conditions shall immediately be reported to Payor. If Provider breaches any of the Terms or Conditions of this Agreement, Provider's access to this information shall be terminated immediately. Violation of these Terms and Conditions may also lead to reprimand, suspension or termination of Provider from Payor, consistent with Payor's credentialing policies.

6. Authorization for Use Compliance Verification. Provider expressly authorizes Payor to electronically access, from time to time, the Work Station to verify Provider's compliance with Section 2 hereof. In connection with such access, Payor shall have the right to verify: (a) the name of Provider; (b) the name of Provider's registered user number; (c) the internet address of the Work Station; and (d) the name of the registered user on the network.

7. Warranty Disclaimer. PROVIDER UNDERSTANDS AND AGREES THAT (A) ANY INFORMATION MADE AVAILABLE IS PROVIDED TO PROVIDER "AS IS" AND (B) MEDECISION AND PAYOR EXPRESSLY DISCLAIM, ANY AND ALL REPRESENTATIONS AND WARRANTIES, WHETHER EXPRESS OR IMPLIED, WHETHER ARISING BY STATUTE, COURSE OF DEALING, USAGE, OR TRADE, INCLUDING BUT NOT LIMITED TO ANY WARRANTY OF ACCURACY, COMPLETENESS, PERFORMANCE, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT OR TITLE.

8. Limitation of Liability. UNDER NO CIRCUMSTANCES WILL MEDECISION OR THE PAYOR BE LIABLE FOR ANY INCIDENTAL, SPECIAL, PUNITIVE OR CONSEQUENTIAL DAMAGES ARISING OUT OF OR IN CONNECTION WITH THIS INFORMATION MEDECISION'S AND PAYOR'S LIABILITY FOR ANY CAUSE OF ACTION ARISING UNDER OR IN CONNECTION WITH THIS INFORMATION OR OTHERWISE (WHETHER ARISING IN TORT, CONTRACT OR OTHERWISE) WILL BE LIMITED TO THE AMOUNT OF LICENSE FEES RECEIVED BY MEDECISION UNDER THE LICENSE AGREEMENT.

9. Patient Care Responsibility. Provider acknowledges and agrees that MEDecision is not engaged in the rendering of medical, health or psychological diagnosis, treatment, evaluation, patient care or any other kind of personal professional services in licensing the PCS System to Payor. The PCS System and the information to be made available are to be used as a tool to assist Provider in connection with Payor's care management program. MEDecision expressly disclaims all responsibility for any liability, loss or risk which is incurred as a consequence, directly or indirectly, of Payor's use of the PCS System.

10. Indemnification. Provider hereby agrees, at Provider's own expense, to indemnify, defend and hold harmless MEDecision and Payor from and against any loss, cost, damages, liability, or expense arising out of or relating to (a) a breach by Provider of the Terms and Conditions of this Agreement, or (b) any violation of any law, regulation or rights of a third party.

11. Miscellaneous. Neither party shall be responsible for any delay or failure of performance resulting from causes beyond its control. This Agreement may be modified and updated from time to time and Provider will be informed of such changes. This Agreement is governed by Pennsylvania law. Provider consents to jurisdiction of the courts in Pennsylvania. Provider may not assign this Agreement. Any noun or pronoun used in this Agreement shall be construed in masculine, feminine or neuter as its sense and use may require.

12. Survival. The provisions of Sections 4, 7, 8, 9, 10, 11, and this Section 12 shall survive termination of this Agreement.

By accessing this information, you represent that you have the authority to do so and acknowledge and agree that you have received a copy of, have read, do understand, and will comply with these Terms and Conditions for Security and Confidentiality of Patient Records and Information.

July 24, 2006

An **Economic Evaluation of Use** of a **Payer-Based Electronic Health Record** within an **Emergency Department**

HealthCore real world insight
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An Economic Evaluation of Use of a Payer-Based Electronic Health Record within an Emergency Department

By Vincent J. Willey, PharmD; Gregory W. Daniel, RPh, MS, MPH

Abstract

Background: Although use of electronic health records (EHR) is being advocated by many in the public and private sectors, a limited number of analyses evaluating the economic impact associated with using EHR have been performed. The hypothesis of this analysis was that the implementation of an EHR within an emergency department (ED) would result in decreased healthcare costs.

Methods: We utilized a retrospective cohort design with matched controls to evaluate the impact of using the Patient Clinical Summary (PCS), a payer-based EHR, in the ED. Data were captured from a health insurer, an emergency department and a care management software and services company. Outcomes analyzed included overall healthcare costs, utilization and costs associated with specific medical services and hospital admission rates. All ED encounter costs were summed from the allowed costs identified from the health insurer. Sensitivity analyses were performed by truncating outlier costs.

Results: A total of 918 PCS-accessed ED encounters and 3,509 control ED encounters were identified. A cost savings of $604 (95% CI: 158-1,051; $p<0.008$) was observed in PCS-accessed ED encounters compared with control ED encounters. While there was no difference in hospital admission rates between the groups, savings were driven by a $4,012 (95% CI: 1,822-6,203; $p<0.001$) difference observed in the 17.7% of ED encounters subsequently leading to a hospitalization. Truncation of costs at $57,247, $7,500 and $12,500 resulted in cost savings of $545 ($p=0.001$), $54 ($p=0.432$) and $171 ($p=0.060$), respectively. Healthcare component costs that contributed statistically significant savings included medical/surgical supplies, laboratory and cardiac catheterization procedures.

Conclusion: Utilization of the PCS EHR within this ED setting resulted in significant cost savings. Further study in larger and more diverse populations is required to verify the absolute overall and component cost savings associated with the PCS.

HealthCore

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INTRODUCTION

The electronic health record (EHR), a comprehensive health record that is accessible to all health care providers treating an individual patient, has often been suggested as an important step in the improvement of the US healthcare system.[1] The topic has reached the highest levels of industry and government, including the call by the President on April 27, 2004 for the majority of Americans to have interoperable EHRs within the next decade.[2] A recent survey of physicians shows that although the number having clinical information technology available has increased in the last 5 years, only half have any access to technologies for clinical activities such as exchanging clinical data and accessing patient notes.[3] Although EHRs have been shown to have beneficial impacts on quality and cost of patient care in a variety of settings, expanded study is essential to explore the many facets of this issue.[4,5,6,7,8,9]

Two issues that arise in the development of an EHR are what data sources should be used and what clinical setting should the technology be implemented in first. Ultimately, the optimal EHR will contain information from various medical providers, healthcare payers and the patients themselves. Each data source has numerous strengths and weaknesses when utilized in isolation, although the integration of the three provides a powerful combination of data that can be transformed into actionable knowledge by the clinician. However, the availability of these data sources is varied and a step wise approach to building the EHR with those data that are readily available may be the most practical approach.

In terms of which clinical settings may make ideal initial candidates for implementation, the emergency department has many qualities that would make it an excellent first choice. Few clinical settings (and subsequently patients) suffer from the

lack of comprehensive clinical data in greater magnitude than the emergency department. Clinical information is often lacking due to lack of coordination with outside medical providers, suboptimal knowledge or communication of health issues by patients or family members and the overall urgency of the situation requiring expedited clinical decision making. [10]

Our hypothesis was that the implementation of a payer-based health record to provide access to clinical data not otherwise available within an emergency department would result in decreased healthcare costs. In the fall of 2005, an EHR derived from health insurer claims data was implemented within the emergency department of a level 1 regional trauma center. We utilized a retrospective cohort design with matched controls to assess the effects of access to the EHR in the emergency department setting on overall health payer and patient costs, hospital admissions, and on utilization of specific medical services and their associated costs.

METHODS

Data sources

This retrospective cohort design with matched controls analysis of emergency department (ED) encounters from January 1, 2004 to February 17, 2006 utilized integrated data from the ED, health insurance plan, and a private care management software and services company. All ED encounters used in this study were within the Christiana Care Health System (CCHS) related to members of a health benefits company.

CCHS is one of the largest not-for-profit healthcare providers in the Mid-Atlantic region, serving all of Delaware and portions of seven counties bordering the state in Pennsylvania, Maryland and New Jersey. CCHS comprises two hospitals with over

50,000 annual admissions and one of the busiest emergency departments in the country with approximately 140,000 visits, including the regional level 1 trauma center.

MEDecision, Inc. is a private software and services company with a focus on collaborative care management, a concept that sharing common patient data accessed at the point of care by all of a patient's medical providers will facilitate improved patient outcomes and reduce health care costs. They have developed the Patient Clinical Summary (PCS), a tool that applies proprietary data summarization, clinical validation and "clinical intelligence" algorithms to payer-based administrative data and transforms it into useful clinical information for health care providers. The PCS provides clinical information such as inpatient and outpatient diagnoses assigned by all medical providers, presence of laboratory and diagnostic tests (but not results) and prescription medications filled at all pharmacies paid for by the health insurer. Appendix A provides a sample PCS report for a fictitious patient.

Identification of ED Encounters

MEDecision, Inc. partnered with a health benefits company and CCHS to provide PCSs to ED personnel beginning in September, 2005. The workflow within the CCHS ED was such that upon initial presentation of the health benefits company's member, a registration clerk accesses the MEDecision PCS system to determine the existence of a PCS. If such a record exists, the clerk would download the summary and place it on the patient chart. The triage nurse would then transcribe the clinical information into CCHS admission forms that would subsequently be added to the medical chart for ED physician review.

All PCS accesses for the health benefits company's members between September 1, 2005 and February 17, 2006 were identified by MEDecision, Inc. and then linked to corresponding ED encounters within 1 day of the PCS access using medical claims data. This allowed for situations such as late night ED visits and related early morning PCS accesses. In order to identify the controls, ED encounters within the CCHS system with no corresponding PCS accesses were identified using the health benefits company's medical claims between January 1, 2004 and February 17, 2006. Individual patients with PCS-accessed ED encounters were only permitted to contribute control ED encounters between January 1, 2004 and August 31, 2005 in order to prevent information obtained from a PCS to be used by ED personnel for subsequent non PCS-accessed ED visits. ED encounters were identified by the presence of facility charges (HCFA Uniform Bill-92 (UB-92) codes 450-459) and claims for ED evaluation and management visits (Current Procedural Terminology (CPT) codes 99281-99285, 99288).

To ensure that control ED encounters were similar in scope to PCS-accessed encounters to the extent possible, up to 5 control encounters per PCS encounter were selected by using covariate matching. Match covariates included age (within 5 years), gender, health insurance line of business, and the Emergency Severity Index (ESI). The ESI is a 5-level emergency department triage algorithm that provides clinically relevant stratification of patients into five groups from 1 (most urgent) to 5 (least urgent) on the basis of acuity and resource needs. Only ED visits with an ESI triage score available were retained for inclusion in the match. The matching procedure used in this study was matching without replacement in order to increase the precision of our estimates and statistical power.

Resource Utilization

The primary outcome for this study was total health plan allowed amounts (reflect amounts paid by the health plan and patient) for each ED encounter. Because ED charges and inpatient charges are combined into a single bill for patients admitted into the hospital, ED-specific charges were indistinguishable from charges for services incurred in the hospital inpatient setting. For this reason, and since information obtained from the PCS may impact initial hospital care, health plan allowed amounts for the first day of the hospitalization (i.e., day after the identified ED encounter) were included for ED encounters in which patients were admitted into the hospital. In addition, inpatient costs associated with the entire span of the hospitalization (including the first day) and paid in one lump sum were pro-rated and allocated to the first day by dividing by the number of days spent in the hospital. Discharged ED encounters were defined as ED visits in which the patient was not admitted into the hospital within one day after the ED encounter.

Secondary outcomes included the use of health plan allowed amounts for select component services or resources, including: pharmacy, diagnostic radiology, laboratory, minor surgery and operating room, medical and surgical supplies, room and board, professional fees for non-ED personnel, ED professional fees, and ED facility charges. Although PCS and control ED encounters were matched on ESI triage scores assigned upon entry into the ED, these scores may not fully reflect the severity of the complicating illness that may have been uncovered after complete examination. To assess the overall severity, rates of inpatient admission, as well as intensive care unit (ICU) or coronary care unit (CCU) admission rates and plan allowed amounts, and the hospital length-of-

stay were collected as secondary outcomes. Appendix B includes specific UB92 and CPT codes used to identify these components.

Since the majority of control ED encounters were collected over the 20 months prior to PCS-accessed encounters, all health plan allowed amounts were adjusted to 2006 US dollars using the actual inflation of allowed amounts from the health benefits company to CCHS.

Statistical analysis

Group differences between PCS-accessed ED encounters and control encounters on match variables were tested with independent t-tests and chi-squared tests to ensure match success. To assess the extent to which the match resulted in similar comparison groups on non-match characteristics, comparisons were further made on the primary diagnosis on ED claims for each encounter. The top twelve three-digit International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) codes among the PCS-accessed encounters and among the control encounters were compared using chi-squared tests.

Mean cost savings associated with the PCS were calculated as the difference in total plan allowed amounts for the ED encounters (including the first day of hospitalization if admitted) between the PCS-accessed and control encounters. Statistical significance was assessed using ordinary least squares (OLS) regression-based Wald tests. We specified the Huber/White/sandwich (robust) estimator of variance with clustering on matched groups to relax the identical distribution assumption and the assumption of independence of observations within matched groups. [11,12]

ED encounters that resulted in hospital admission were likely to have higher total plan allowed amounts than encounters not resulting in admission. A sensitivity analysis was performed to examine the impact of extreme costs by truncating total allowed amounts for all ED encounters (encounters resulting in either discharge or admission) at three different levels. First, total allowed amounts were truncated at the highest amount for discharged ED encounters ($57,247). Second, the 99th percentile of total allowed amounts for ED encounters resulting in a discharge ($7,500) was used as a conservative value. Third, graphical representation of the distribution of total allowed amounts for discharged ED encounters was used to determine the inflection point where spread of extreme values between $7,500 and $57,247 visually increases (determined to be at approximately $12,000). A subsequent sensitivity analysis was also performed using actual plan paid amounts, which do not reflect patient out-of-pocket components, for comparisons on total and component ED costs. This study was conducted in accordance with and was approved by the Christiana Care Health System Institutional Review Board prior to initiation of any work. All analyses were performed at the 0.05 alpha level using Stata version 8.2, StataCorp, College Station, TX.

RESULTS

Figure 1 illustrates the flow of ED encounters for final study analysis inclusion. A total of 919 PCS-accessed ED encounters, out of 1,313 initially identified, were matched within 1 day of an ED encounter and had a corresponding ESI triage score available. From 13,491 unique control ED encounters with an ESI score (from 16,763 initially identified from the health benefits company's claims), 3,590 were matched to 918 PCS-accessed encounters since one PCS-accessed encounter could not be matched to any of the potential controls.

A total of 3,807 individual patients contributed the 4,508 ED encounters (3,076 individual patients contributed to control ED encounters, 869 individual patients contributed PCS-accessed ED encounters. 138 contributed at least one control and one PCS-accessed encounter). Overall 12.5% (474/3,807) of the selected patients contributed multiple ED encounters.

As displayed in Table 1, control ED encounters were selected in a manner that resulted in no statistically significant differences with PCS-accessed cases on match variables. Among the twelve most common primary diagnoses among the PCS-accessed encounters and among control encounters, symptoms of the respiratory system and other chest symptoms (ICD-9-CM 786) was the most common (11.3% and 12.2%, respectively; p=0.455). The only statistically significant difference in frequency of diagnoses observed between the PCS-accessed and control encounters was with respect to having a diagnosis of kidney and ureter calculus (ICD-9-CM 592; 3.4% and 2.1%, respectively; p=0.029).

Frequencies of selected components by PCS-accessed ED encounters and control encounters are displayed in Figure 2. Between 60 and 70% of all encounters involved claims for diagnostic radiology, laboratory, and pharmacy services. Among all selected components, the only statistically significant difference observed between PCS-accessed case encounters and control encounters was with the frequency of having a laboratory claim (65.4% vs. 60.2%, p=0.005). As measures of the overall ED encounter severity (beyond initial triage), the rates of inpatient admission and ICU or CCU admission were not statistically different. Furthermore, the lengths-of-stay for the 798 (17.7%) ED encounters resulting in hospital admission were not statistically different between PCS-

accessed and control ED encounters (2.97 ± 2.88 [standard deviation] days vs. 3.23 ± 3.31 days, p=0.346, data not shown in table).

Table 2 displays the total mean health plan allowed amounts for PCS-accessed and control ED encounters, as well as the estimated cost savings associated with the PCS. Among all ED encounters, the mean cost savings was $604 (p=0.008). When examining ED encounters resulting in discharge and hospital admission separately, no cost savings were observed among discharged ED encounters (-$12, p=0.840) whereas, cost savings of $4,012 (p<0.001) were observed among admitted ED encounters. A summary of the cost savings associated with the PCS for the selected component resources of total ED allowed amounts for all ED encounters are displayed in Table 3. The largest savings was associated with medical/surgical supplies ($214, p<0.001). Other statistically significant (p<0.05) contributors to cost savings were laboratory and cardiac catheterization procedures.

The results from the sensitivity analysis to determine the robustness of study findings to extreme costs are displayed in Table 4. The highest plan allowed amount for an ED encounter that did not result in hospital admission was $57,247. After truncating all total ED allowed amounts for encounters that resulted in a hospitalization above this value to $57,247 (12 ED encounters affected; 11 control encounters, 1 PCS encounter), cost savings of $545 (p=0.001) were observed. The 99th percentile of total ED allowed amounts for discharged ED encounters was $7,500 (99th percentile). Using this as a truncation value affected 346 ED encounters (295 control encounters, 51 PCS encounters). The resulting cost savings associated with the PCS was $54 (p=0.432). however the sample size for this study was such that we only had 11% power to detect a $54 difference as significant. Figure 3a illustrates the distribution of total ED allowed

amounts by discharge/admission status. The distribution omits values above $60,000 to allow better visual inspection. The distribution of ED allowed amounts between $6,000 and $60,000 (Figure 3b) revealed that at approximately $12,000, the spread of values among the discharged ED encounters visually increases (Figure 3b). Using this as the truncation value affected 170 ED encounters (154 control encounters and 16 PCS encounters) and resulted in a cost savings of $171 (p=0.060). Again, this study only had 43% power to detect a $171 difference given the sample size.

Cost savings associated with the PCS were also examined using inflation adjusted plan paid amounts (data not shown). Overall cost savings obtained by using plan paid amounts were similar to those observed when using allowed amounts. Similar effects of the truncation values as with the plan allowed amounts were also observed when analyzing paid amounts.

DISCUSSION

This study is among the first to assess the economic outcomes associated with ED use of an EHR that contained both inpatient and outpatient data from medical providers outside of the health system being studied. Specifically, we evaluated the PCS, an EHR that transformed payer-based, administrative medical and pharmacy claims data into clinical information that aided the emergency department in their care of patients utilizing a retrospective cohort design with matched controls. The PCS provided clinically validated information such as inpatient and outpatient diagnoses, presence of laboratory and diagnostic tests (but not results) and prescription medications filled at all pharmacies paid for by the health insurer at the time the patient was being clinically evaluated. This study did not evaluate the impact of providing raw claims data to the ED. Therefore, no

comment can be made as to the potential economic impact of providing that type of information.

Compared to control ED encounters, PCS-accessed ED encounters resulted in a statistically significant cost savings of $604. Even when the highest values were truncated using methodology similar to previous published literature,[4] PCS-accessed ED encounters resulted in a statistically significant cost savings of $545. When truncation values were lowered during our sensitivity analysis, non-statistically significant cost savings of $54 (power = 11%) and $171 (power = 43%) were calculated. To place the opportunity for potential savings in context to the overall United States (US) population, the Centers for Disease Control (CDC) estimates that there were 110.2 million visits to the ED in the US in 2004. (National Hosp Amb Med Care Surv: 2004 ED Sum, Number 372, June 23, 2006)

The cost savings observed in the PCS-accessed patients were driven by the subset of patients that were subsequently admitted to the hospital, as there was a $4,012 difference between the groups. In an attempt to further understand what expenditures were driving the cost savings, all clinically and economically meaningful component costs were evaluated. Our hypothesis was that the PCS might produce a savings by providing information to the treating physician that would allow him/her to avoid various medical services. A statistically significant cost savings was calculated for the following types of services in the PCS-accessed ED encounters: laboratory, cardiac catheterizations, medical/surgical supplies, and other. Of note, professional fees for the ED physicians showed a statistically significant increase in the PCS-accessed ED encounters compared with the control ED encounters. Hospital admission rates, ICU/CCU admission rates and lengths of stay were similar between the groups.

One study that evaluated the sharing of clinical data from outside the institution for use in the ED was performed by Overhage and colleagues.[4] They observed a $26 costs savings ($p = 0.03$) in one institution and a non-significant $3 increase ($p = 0.76$) in the other institution between intervention and control patients, which is a much smaller cost difference than we observed. However, there were many differences in the study compared to ours, including the fact that the clinical data was not utilized in a large percent of the intervention cases, the hospital billing system and hospital charges were utilized for the economic evaluation and the study was performed a decade earlier. Also unlike our study, prior research has not demonstrated that specific cost categories/components were responsible for overall cost savings.[4,13] However, our study did find similar results to previous research that demonstrated a decrease in laboratory charges/costs associated with access to a computerized medical record.[5,6,7,8]

Several limitations are worthy of mention regarding our research. First, we utilized an observational design for the study since the implementation of the PCS did not allow for a randomized, controlled design. However, we did match our control group on meaningful demographic (age and gender), health plan design (health insurer line of business) and clinical (ESI score assigned by the ED triage nurse) variables. In addition, although our control ED encounters were both concurrent and historical in relation to our PCS-accessed encounters, the time frame was less than 2 years and all costs were adjusted to 2006 dollars. The results were not sensitive to this inflation adjustment. We chose to use allowed amounts to capture the societal perspective of the costs/cost savings since allowed amounts capture both the health plan payment and the patient out of pocket payment responsibility to the ED department. However, the use of health plan paid

INTRODUCTION

The electronic health record (EHR), a comprehensive health record that is accessible to all health care providers treating an individual patient, has often been suggested as an important step in the improvement of the US healthcare system.[1] The topic has reached the highest levels of industry and government, including the call by the President on April 27, 2004 for the majority of Americans to have interoperable EHRs within the next decade.[2] A recent survey of physicians shows that although the number having clinical information technology available has increased in the last 5 years, only half have any access to technologies for clinical activities such as exchanging clinical data and accessing patient notes.[3] Although EHRs have been shown to have beneficial impacts on quality and cost of patient care in a variety of settings, expanded study is essential to explore the many facets of this issue.[4,5,6,7,8,9]

Two issues that arise in the development of an EHR are what data sources should be used and what clinical setting should the technology be implemented in first. Ultimately, the optimal EHR will contain information from various medical providers, healthcare payers and the patients themselves. Each data source has numerous strengths and weaknesses when utilized in isolation, although the integration of the three provides a powerful combination of data that can be transformed into actionable knowledge by the clinician. However, the availability of these data sources is varied and a step wise approach to building the EHR with those data that are readily available may be the most practical approach.

In terms of which clinical settings may make ideal initial candidates for implementation, the emergency department has many qualities that would make it an excellent first choice. Few clinical settings (and subsequently patients) suffer from the

lack of comprehensive clinical data in greater magnitude than the emergency department. Clinical information is often lacking due to lack of coordination with outside medical providers, suboptimal knowledge or communication of health issues by patients or family members and the overall urgency of the situation requiring expedited clinical decision making.[10]

Our hypothesis was that the implementation of a payer-based health record to provide access to clinical data not otherwise available within an emergency department would result in decreased healthcare costs. In the fall of 2005, an EHR derived from health insurer claims data was implemented within the emergency department of a level 1 regional trauma center. We utilized a retrospective cohort design with matched controls to assess the effects of access to the EHR in the emergency department setting on overall health payer and patient costs, hospital admissions, and on utilization of specific medical services and their associated costs.

METHODS

Data sources

This retrospective cohort design with matched controls analysis of emergency department (ED) encounters from January 1, 2004 to February 17, 2006 utilized integrated data from the ED, health insurance plan, and a private care management software and services company. All ED encounters used in this study were within the Christiana Care Health System (CCHS) related to members of a health benefits company.

CCHS is one of the largest not-for-profit healthcare providers in the Mid-Atlantic region, serving all of Delaware and portions of seven counties bordering the state in Pennsylvania, Maryland and New Jersey. CCHS comprises two hospitals with over

50,000 annual admissions and one of the busiest emergency departments in the country with approximately 140,000 visits, including the regional level 1 trauma center.

MEDecision, Inc. is a private software and services company with a focus on collaborative care management, a concept that sharing common patient data accessed at the point of care by all of a patient's medical providers will facilitate improved patient outcomes and reduce health care costs. They have developed the Patient Clinical Summary (PCS), a tool that applies proprietary data summarization, clinical validation and "clinical intelligence" algorithms to payer-based administrative data and transforms it into useful clinical information for health care providers. The PCS provides clinical information such as inpatient and outpatient diagnoses assigned by all medical providers, presence of laboratory and diagnostic tests (but not results) and prescription medications filled at all pharmacies paid for by the health insurer. Appendix A provides a sample PCS report for a fictitious patient.

Identification of ED Encounters

MEDecision, Inc. partnered with a health benefits company and CCHS to provide PCSs to ED personnel beginning in September, 2005. The workflow within the CCHS ED was such that upon initial presentation of the health benefits company's member, a registration clerk accesses the MEDecision PCS system to determine the existence of a PCS. If such a record exists, the clerk would download the summary and place it on the patient chart. The triage nurse would then transcribe the clinical information into CCHS admission forms that would subsequently be added to the medical chart for ED physician review.

All PCS accesses for the health benefits company's members between September 1, 2005 and February 17, 2006 were identified by MEDecision, Inc. and then linked to corresponding ED encounters within 1 day of the PCS access using medical claims data. This allowed for situations such as late night ED visits and related early morning PCS accesses. In order to identify the controls, ED encounters within the CCHS system with no corresponding PCS accesses were identified using the health benefits company's medical claims between January 1, 2004 and February 17, 2006. Individual patients with PCS-accessed ED encounters were only permitted to contribute control ED encounters between January 1, 2004 and August 31, 2005 in order to prevent information obtained from a PCS to be used by ED personnel for subsequent non PCS-accessed ED visits. ED encounters were identified by the presence of facility charges (HCFA Uniform Bill-92 (UB-92) codes 450-459) and claims for ED evaluation and management visits (Current Procedural Terminology (CPT) codes 99281-99285, 99288).

To ensure that control ED encounters were similar in scope to PCS-accessed encounters to the extent possible, up to 5 control encounters per PCS encounter were selected by using covariate matching. Match covariates included age (within 5 years), gender, health insurance line of business, and the Emergency Severity Index (ESI). The ESI is a 5-level emergency department triage algorithm that provides clinically relevant stratification of patients into five groups from 1 (most urgent) to 5 (least urgent) on the basis of acuity and resource needs. Only ED visits with an ESI triage score available were retained for inclusion in the match. The matching procedure used in this study was matching without replacement in order to increase the precision of our estimates and statistical power.

Resource Utilization

The primary outcome for this study was total health plan allowed amounts (reflect amounts paid by the health plan and patient) for each ED encounter. Because ED charges and inpatient charges are combined into a single bill for patients admitted into the hospital, ED-specific charges were indistinguishable from charges for services incurred in the hospital inpatient setting. For this reason, and since information obtained from the PCS may impact initial hospital care, health plan allowed amounts for the first day of the hospitalization (i.e., day after the identified ED encounter) were included for ED encounters in which patients were admitted into the hospital. In addition, inpatient costs associated with the entire span of the hospitalization (including the first day) and paid in one lump sum were pro-rated and allocated to the first day by dividing by the number of days spent in the hospital. Discharged ED encounters were defined as ED visits in which the patient was not admitted into the hospital within one day after the ED encounter.

Secondary outcomes included the use of health plan allowed amounts for select component services or resources, including: pharmacy, diagnostic radiology, laboratory, minor surgery and operating room, medical and surgical supplies, room and board, professional fees for non-ED personnel, ED professional fees, and ED facility charges. Although PCS and control ED encounters were matched on ESI triage scores assigned upon entry into the ED, these scores may not fully reflect the severity of the complicating illness that may have been uncovered after complete examination. To assess the overall severity, rates of inpatient admission, as well as intensive care unit (ICU) or coronary care unit (CCU) admission rates and plan allowed amounts, and the hospital length-of-

stay were collected as secondary outcomes. Appendix B includes specific UB92 and CPT codes used to identify these components.

Since the majority of control ED encounters were collected over the 20 months prior to PCS-accessed encounters, all health plan allowed amounts were adjusted to 2006 US dollars using the actual inflation of allowed amounts from the health benefits company to CCHS.

Statistical analysis

Group differences between PCS-accessed ED encounters and control encounters on match variables were tested with independent t-tests and chi-squared tests to ensure match success. To assess the extent to which the match resulted in similar comparison groups on non-match characteristics, comparisons were further made on the primary diagnosis on ED claims for each encounter. The top twelve three-digit International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) codes among the PCS-accessed encounters and among the control encounters were compared using chi-squared tests.

Mean cost savings associated with the PCS were calculated as the difference in total plan allowed amounts for the ED encounters (including the first day of hospitalization if admitted) between the PCS-accessed and control encounters. Statistical significance was assessed using ordinary least squares (OLS) regression-based Wald tests. We specified the Huber/White/sandwich (robust) estimator of variance with clustering on matched groups to relax the identical distribution assumption and the assumption of independence of observations within matched groups. [11,12]

ED encounters that resulted in hospital admission were likely to have higher total plan allowed amounts than encounters not resulting in admission. A sensitivity analysis was performed to examine the impact of extreme costs by truncating total allowed amounts for all ED encounters (encounters resulting in either discharge or admission) at three different levels. First, total allowed amounts were truncated at the highest amount for discharged ED encounters ($57,247). Second, the 99th percentile of total allowed amounts for ED encounters resulting in a discharge ($7,500) was used as a conservative value. Third, graphical representation of the distribution of total allowed amounts for discharged ED encounters was used to determine the inflection point where spread of extreme values between $7,500 and $57,247 visually increases (determined to be at approximately $12,000). A subsequent sensitivity analysis was also performed using actual plan paid amounts, which do not reflect patient out-of-pocket components, for comparisons on total and component ED costs. This study was conducted in accordance with and was approved by the Christiana Care Health System Institutional Review Board prior to initiation of any work. All analyses were performed at the 0.05 alpha level using Stata version 8.2, StataCorp, College Station, TX.

RESULTS

Figure 1 illustrates the flow of ED encounters for final study analysis inclusion. A total of 919 PCS-accessed ED encounters, out of 1,313 initially identified, were matched within 1 day of an ED encounter and had a corresponding ESI triage score available. From 13,491 unique control ED encounters with an ESI score (from 16,763 initially identified from the health benefits company's claims), 3,590 were matched to 918 PCS-accessed encounters since one PCS-accessed encounter could not be matched to any of the potential controls.

A total of 3,807 individual patients contributed the 4,508 ED encounters (3,076 individual patients contributed to control ED encounters, 869 individual patients contributed PCS-accessed ED encounters, 138 contributed at least one control and one PCS-accessed encounter). Overall 12.5% (474/3,807) of the selected patients contributed multiple ED encounters.

As displayed in Table 1, control ED encounters were selected in a manner that resulted in no statistically significant differences with PCS-accessed cases on match variables. Among the twelve most common primary diagnoses among the PCS-accessed encounters and among control encounters, symptoms of the respiratory system and other chest symptoms (ICD-9-CM 786) was the most common (11.3% and 12.2%, respectively; p=0.455). The only statistically significant difference in frequency of diagnoses observed between the PCS-accessed and control encounters was with respect to having a diagnosis of kidney and ureter calculus (ICD-9-CM 592; 3.4% and 2.1%, respectively; p=0.029).

Frequencies of selected components by PCS-accessed ED encounters and control encounters are displayed in Figure 2. Between 60 and 70% of all encounters involved claims for diagnostic radiology, laboratory, and pharmacy services. Among all selected components, the only statistically significant difference observed between PCS-accessed case encounters and control encounters was with the frequency of having a laboratory claim (65.4% vs. 60.2%, p=0.005). As measures of the overall ED encounter severity (beyond initial triage), the rates of inpatient admission and ICU or CCU admission were not statistically different. Furthermore, the lengths-of-stay for the 798 (17.7%) ED encounters resulting in hospital admission were not statistically different between PCS-

accessed and control ED encounters (2.97 ± 2.88 [standard deviation] days vs. 3.23 ± 3.31 days, p=0.346, data not shown in table).

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amounts by discharge/admission status. The distribution omits values above $60,000 to allow better visual inspection. The distribution of ED allowed amounts between $6,000 and $60,000 (Figure 3b) revealed that at approximately $12,000, the spread of values among the discharged ED encounters visually increases (Figure 3b). Using this as the truncation value affected 170 ED encounters (154 control encounters and 16 PCS encounters) and resulted in a cost savings of $171 (p=0.060). Again, this study only had 43% power to detect a $171 difference given the sample size.

Cost savings associated with the PCS were also examined using inflation adjusted plan paid amounts (data not shown). Overall cost savings obtained by using plan paid amounts were similar to those observed when using allowed amounts. Similar effects of the truncation values as with the plan allowed amounts were also observed when analyzing paid amounts.

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This study is among the first to assess the economic outcomes associated with ED use of an EHR that contained both inpatient and outpatient data from medical providers outside of the health system being studied. Specifically, we evaluated the PCS, an EHR that transformed payer-based, administrative medical and pharmacy claims data into clinical information that aided the emergency department in their care of patients utilizing a retrospective cohort design with matched controls. The PCS provided clinically validated information such as inpatient and outpatient diagnoses, presence of laboratory and diagnostic tests (but not results) and prescription medications filled at all pharmacies paid for by the health insurer at the time the patient was being clinically evaluated. This study did not evaluate the impact of providing raw claims data to the ED. Therefore, no

comment can be made as to the potential economic impact of providing that type of information.

Compared to control ED encounters, PCS-accessed ED encounters resulted in a statistically significant cost savings of $604. Even when the highest values were truncated using methodology similar to previous published literature,[4] PCS-accessed ED encounters resulted in a statistically significant cost savings of $545. When truncation values were lowered during our sensitivity analysis, non-statistically significant cost savings of $54 (power = 11%) and $171 (power = 43%) were calculated. To place the opportunity for potential savings in context to the overall United States (US) population, the Centers for Disease Control (CDC) estimates that there were 110.2 million visits to the ED in the US in 2004. (National Hosp Amb Med Care Surv: 2004 ED Sum, Number 372, June 23, 2006)

The cost savings observed in the PCS-accessed patients were driven by the subset of patients that were subsequently admitted to the hospital, as there was a $4,012 difference between the groups. In an attempt to further understand what expenditures were driving the cost savings, all clinically and economically meaningful component costs were evaluated. Our hypothesis was that the PCS might produce a savings by providing information to the treating physician that would allow him/her to avoid various medical services. A statistically significant cost savings was calculated for the following types of services in the PCS-accessed ED encounters: laboratory, cardiac catheterizations, medical/surgical supplies, and other. Of note, professional fees for the ED physicians showed a statistically significant increase in the PCS-accessed ED encounters compared with the control ED encounters. Hospital admission rates, ICU/CCU admission rates and lengths of stay were similar between the groups.

One study that evaluated the sharing of clinical data from outside the institution for use in the ED was performed by Overhage and colleagues.[4] They observed a $26 costs savings ($p = 0.03$) in one institution and a non-significant $3 increase ($p = 0.76$) in the other institution between intervention and control patients, which is a much smaller cost difference than we observed. However, there were many differences in the study compared to ours, including the fact that the clinical data was not utilized in a large percent of the intervention cases, the hospital billing system and hospital charges were utilized for the economic evaluation and the study was performed a decade earlier. Also unlike our study, prior research has not demonstrated that specific cost categories/components were responsible for overall cost savings.[4,13] However, our study did find similar results to previous research that demonstrated a decrease in laboratory charges/costs associated with access to a computerized medical record.[5,6,7,8]

Several limitations are worthy of mention regarding our research. First, we utilized an observational design for the study since the implementation of the PCS did not allow for a randomized, controlled design. However, we did match our control group on meaningful demographic (age and gender), health plan design (health insurer line of business) and clinical (ESI score assigned by the ED triage nurse) variables. In addition, although our control ED encounters were both concurrent and historical in relation to our PCS-accessed encounters, the time frame was less than 2 years and all costs were adjusted to 2006 dollars. The results were not sensitive to this inflation adjustment. We chose to use allowed amounts to capture the societal perspective of the costs/cost savings since allowed amounts capture both the health plan payment and the patient out of pocket payment responsibility to the ED department. However, the use of health plan paid

amounts resulted in no changes in statistical significance compared with allowed amounts, although the absolute cost savings were reduced.

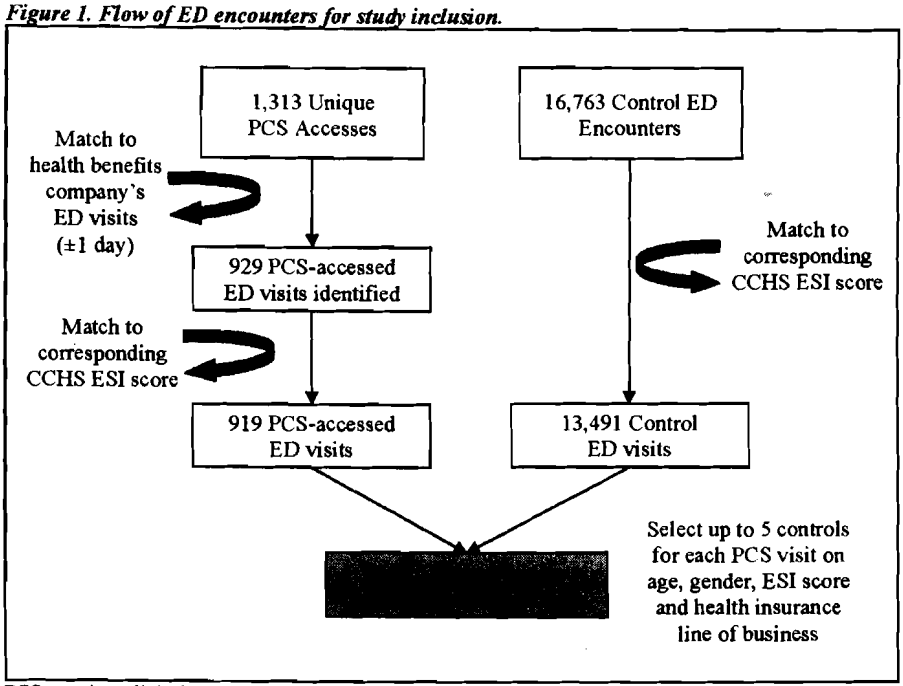
We believe the most important question to ask when reviewing these results are "were the cost savings due to unobserved differences between the groups not accounted for in the matching process" since our cost savings are greater than has been demonstrated in other computer-based, information technology intervention studies. Specifically, was the medical condition "severity" in the control ED encounter group greater than in the PCS-accessed ED encounter group? Although this can not be completely discounted, we do believe that several important indicators show that the groups did not differ greatly in this aspect. In order to address the medical condition severity of an individual patient ED encounter upon presentation to the ED, we utilized the ESI score provided by the triage nurse in the matching criteria. Also, hospital admission rates, ICU/CCU admission rates and lengths of stay were not statistically significant between the groups although they were not specifically included in the match criteria. Hospital admission rates, ICU/CCU admission rates and lengths of stay may serve as a proxy to describe the medical condition severity of the patient as their ED encounter progressed after triage and through hospitalization if the patient was admitted. In addition, although not included in the match criteria, the primary diagnoses for the ED encounter via ICD-9 administrative claims data were similar between the groups.

Also, when lower truncation values were used, statistical significance for the costs savings was lost. However, the post-hoc power calculations revealed a less than optimal power to detect a statistically significant cost difference. We believe this justifies the need to continue to evaluate the use of the PCS in the ED setting. In addition to increasing the study population, since only one ED was included in our study, we believe

research within other ED settings utilizing the PCS will provide greater confidence in the robustness and generalizability of these results.

In conclusion, utilization of the PCS EHR within this ED setting resulted in significant cost savings. Further study in larger and more diverse populations is required to verify the absolute overall and component cost savings associated with the PCS. Future study could also encompass assessing the impact of incorporating additional data sources into the creation of the PCS, providing the PCS in other treatment settings, such as physician offices, and the impact of the PCS on health quality outcomes. However, these data show the potential economic savings that may be realized due to the availability of the additional clinical data provided by the PCS for a patient that presents to the ED.

Figure 1. Flow of ED encounters for study inclusion.



PCS = patient clinical summary; ED = emergency department; CCHS = Christiana Care Health System; ESI = emergency severity index

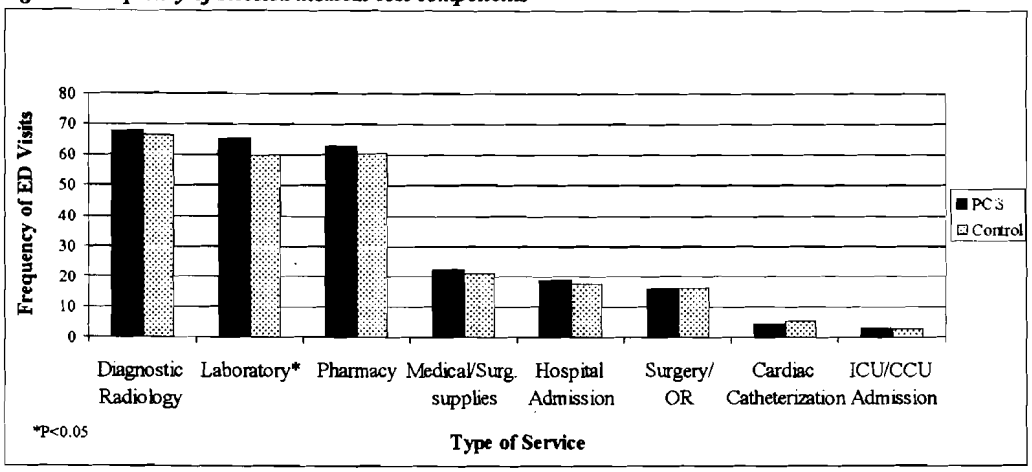
Table 1. Characteristics of PCS-accessed ED encounters and control ED encounters

Description	PCS-accessed ED encounters	Control ED Encounters	P-value
Number of ED encounters	918	3590	
Age, mean ± SD	37.2 ± 17.0	37.2 ± 16.8	0.943
Female, %	51.7	52	0.875
Health insurance line of business, %			0.986
IPA	39.2	40.1	
PPO	31.4	30.0	
Medicare	17.5	17.9	
Traditional	3.8	3.9	
Other	8.1	8.1	
Triage Severity Score			0.916
1 (most urgent)	0.1	0.1	
2	22.7	21.9	
3	54.4	55.1	
4	20	20.5	
5 (least urgent)	2.8	2.4	
ED Encounter Primary Diagnosis			
Symptoms involving respiratory system and other chest symptoms	11.3	12.2	0.455
Other symptoms involving abdomen and pelvis	8.7	7.0	0.079
General symptoms	5.0	5.1	0.888
Calculus of kidney and ureter	3.4	2.1	0.029
Other open wound of head	2.3	1.9	0.480
Symptoms involving head and neck	2.1	2.1	0.987
Other cellulitis and abscess	2.0	1.3	0.160
Sprains and strains of other and unspecified parts of back	2.0	2.1	0.848
Symptoms involving urinary system	1.7	1.2	0.195
Contusion of face, scalp, and neck except eye(s)	1.7	1.1	0.089
Symptoms involving digestive system	1.6	2.3	0.226
Asthma	0.9	1.7	0.061

Cardiac dysrhythmias	1.0	1.4	0.327
Open wound of finger(s)	1.1	1.3	0.639

PCS = patient clinical summary; ED = emergency department; SD = standard deviation; IPA = independent practice association; PPO = preferred provider organization; ESI = emergency severity index

Figure 2. Frequency of selected medical cost components



PCS = patient clinical summary; ED = emergency department; OR = operating room; ICU/CCU = intensive care unit/coronary care unit

Table 2. Mean total plan allowed amounts and cost savings (control ED encounters – PCS-accessed ED encounters) by type of ED encounter

	PCS-accessed ED encounters	Control ED Encounters	Cost Savings	95% CI	P-value
Overall	2,309	2,913	604	158 to 1,051	0.008
Discharged ED encounters*	1,199	1,187	-12	-124 to 101	0.840
Admitted ED encounters**	7,089	11,101	4,012	1,822 to 6,203	<0.001

Results are displayed in 2006 US dollars; PCS = patient clinical summary; ED = emergency department; CI = confidence interval; *Discharged ED encounters include only ED visits in which the patient was not admitted into the hospital within 1 day of the ED encounter; **Admitted ED encounters include ED visits that resulted in the patient being admitted into the hospital within 1 day of the ED encounter

Table 3. Mean plan allowed amounts for component resources and cost savings (control ED encounters – PCS-accessed ED encounters)

	PCS-accessed ED encounters	Control ED Encounters	Cost Savings	95% CI	P-value
Pharmacy	234	332	98	-73 to 268	0.261
Laboratory	302	377	75	12 to 139	0.021
Diagnostic radiology	375	391	16	-40 to 71	0.587
CT scans	160	167	7	-19 to 33	0.604
MRI scans	55	38	-17	-40 to 5	0.127
Cardiac catheterizations	109	186	77	15 to 138	0.015
Surgery/OR/ recovery	181	240	59	-2 to 120	0.058
Medical/surgical supplies	137	351	214	111 to 317	<0.001
ICU/CCU	36	34	-2	-21 to 15	0.763
Room & Board	105	94	-11	-27 to 5	0.182
Non-ED professional	68	60	-8	-18 to 1	0.087
ED professional fees	197	162	-35	-43 to -27	<0.001
Facility charges	342	349	7	-8 to 21	0.375
Other	390	546	156	54 to 257	0.003

Results are displayed in 2006 US dollars; PCS = patient clinical summary; ED = emergency department; CI = confidence interval; CT = computed tomography; MRI = magnetic resonance imaging; OR = operating room; ICU/CCU = intensive care unit/coronary care unit

Table 4. Sensitivity analysis using various truncation values

	PCS-accessed ED encounters	Control ED Encounters	Cost Savings	95% CI	P-value
Truncation #1: (highest value, $57,247)	2,221	2,766	545	238 to 851	0.001
Truncation #2: (99th percentile, $7,500)	1,854	1,908	54	-81 to 190	0.432
Truncation #3: $12,000 (inflection point, $12,000)	2,007	2,178	171	-7 to 348	0.060

Results are displayed in 2006 US dollars; PCS = patient clinical summary; ED = emergency department; CI = confidence interval

Figure 3a. Distribution of total plan allowed amounts less than $60,000 for all ED encounters by hospital admission status

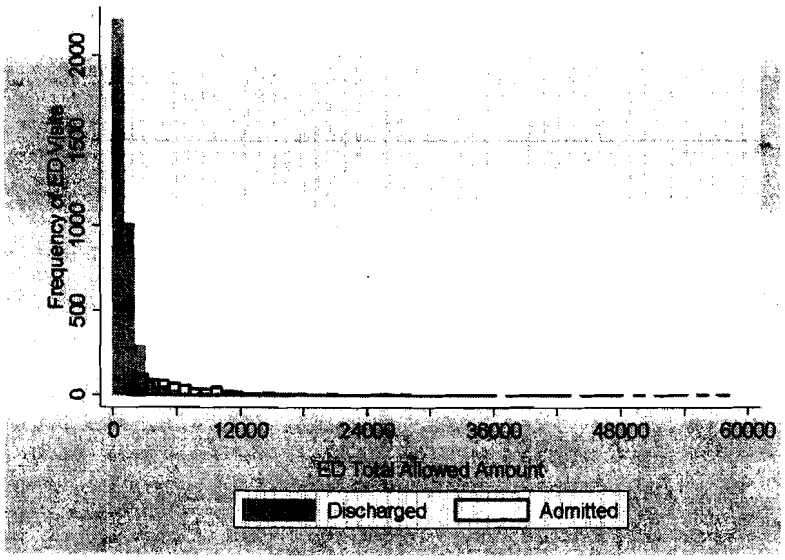
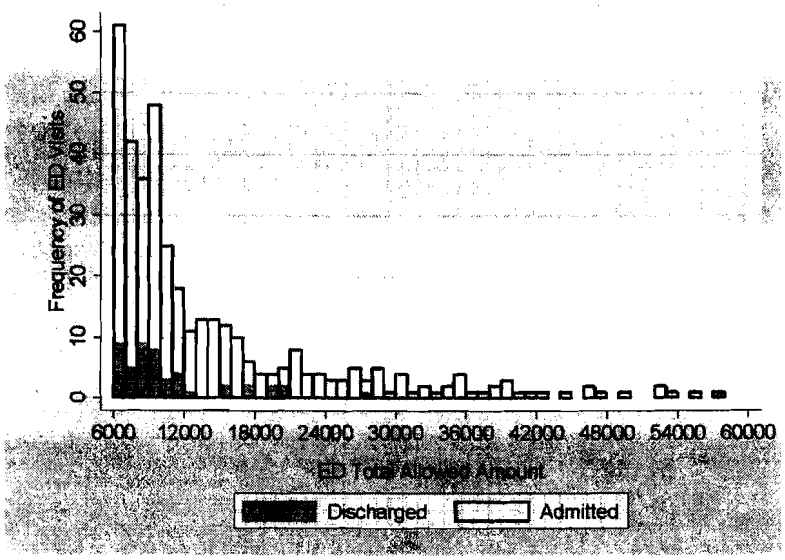


Figure 3b. Distribution of total plan allowed amounts between $6,000 and $60,000 for all ED encounters by hospital admission status



Appendix A:Sample PCS report for a fictitious patient.

Report generated on: 01/28/2005 **Information provided by:** MCO 1
Report based on services provided as of: 12/31/2004

MEDecision

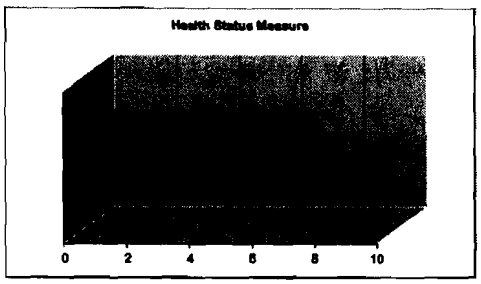
Patient Summary

Name:	BRACERO, DEANGELO	**ID:** JM1QBZJ1H00		**Eligibility:**	01/01/2000 - 01/01/2006
Address:	548 WEADLEY ROAD GULPH MILLS, PA 19406	**DOB:** 01/01/1 957		**Phone (H):**	610-995-9877
		Gender: M		**Phone (W):**	610-269-5200/1154
PCP:	STELLA, BRIAN	**PCP ID:** 610687090		**PCP phone:**	215-463-5254

Case categories: DM - DIABETES

Health Status Measure

The Health Status Measure indicates risk in the next 12 months. 1 is low 10 is high.



Medical Conditions

High Severity

Condition	Start date
GLAUCOMA	04/04/2004
DIABETES MELLITUS	02/20/2004

Medium Severity

Condition	Start date
ABDOMINAL PAIN	04/11/2004
ISCHEMIC HEART DISEASE/ANGINA PECTORIS	04/06/2004
HEART FAILURE (CHF)	01/03/2004
OTHER HEART DISEASE	01/03/2004

MEDecision

Report generated on: 01/28/2005
Information provided by: MCO 1
Report based on services provided as of: 12/31/2004
Name: BRACERO, DEANGELO **ID:** JM1QBZJ1H00 **Eligibility:** 01/01/2000 - 01/01/2006
DOB: 01/01/1957 **Gender:** M

Medical Conditions (continued)

Low Severity

Condition	Start date
OTHER GI TRACT DISEASE	04/11/2004
MUSCLE DISORDER	02/21/2004
RENAL FAILURE	01/10/2004

Inpatient Facility Admissions

Facility	Admit date	Disch. date	Days	Principal DX
KENTON LAFORGE	02/22/2004	03/02/2004	9	250.12 - DIABETES W/KETOACIDOSIS, TYPE II

Emergency Room Visits

PATIENT HAS HAD 0 EMERGENCY ROOM VISITS IN THE PAST 12 MONTHS

Monitored Services

Service	# of services	Last service date	Most recent servicing provider	Phone #
HEMOGLOBIN A1C	3	07/31/2004	GERALDO MCHUGH	610-828-2218
LIPID/CHOLESTEROL TESTING	1	07/31/2004	GERALDO MCHUGH	610-828-2218
GLUCOSE TESTING, BLOOD	5	07/31/2004	DAINA GUSSMAN	215-644-5468
CHEM./METABOLIC PANEL TESTING	51	07/25/2004	DAINA GUSSMAN	215-644-5468
CARDIAC MONITORING (HOLTER)	1	06/20/2004	WENDELL VENDETTI	610-249-5587
SURGICAL PATHOLOGY	1	04/30/2004	DAINA GUSSMAN	215-644-5468
ABDOMINAL ULTRASOUND EXAMS	2	04/17/2004	HEATH SUDDUTH	215-646-9872
URINALYSIS	4	04/16/2004	DAINA GUSSMAN	215-644-5468
AMYLASE (SERUM) ASSAY	2	04/16/2004	DAINA GUSSMAN	215-644-5468
CBC AND COMPONENT COUNTS	4	04/16/2004	DAINA GUSSMAN	215-644-5468
ELECTROCARDIOGRAM (ECG)	1	04/05/2004	WENDELL VENDETTI	610-249-5587
HEART ECHO EXAM	3	03/01/2004	WENDELL VENDETTI	610-249-5587
CALCIUM ASSAY	4	02/23/2004	DAINA GUSSMAN	215-644-5468

Report generated on: 01/28/2005
Information provided by: MCO 1
Report based on services provided as of: 12/31/2004
Name: BRACERO, DEANGELO
DOB: 01/01/1957

ID: JM1QBZJ1H00
Gender: M

Eligibility: 01/01/2000 - 01/01/2006

Monitored Services (continued)

Service	# of services	Last service date	Most recent servicing provider	Phone #
CARDIOVASCULAR STRESS TEST	2	02/22/2004	WENDELL VENDETTI	610-249-5587

Medications

Medication class	# fills	Last fill date
CARVEDILOL/COREG	9	12/28/2004
ACE INHIBITORS	9	12/28/2004
PIOGLITAZONE/ACTOS	8	12/28/2004
LANSOPRAZOLE/PREVACID	7	12/10/2004
AMOXICILLIN PREPARATIONS	1	04/29/2004
OSMOTIC LAXATIVE/BOWEL PREPS	1	04/17/2004
LOOP DIURETICS	3	04/13/2004
INSULIN	2	03 /26/2004
NEEDLES&SYRINGES	1	03/09/2004
AMOX K CLAVULANATE/AUGMENTIN	1	03/02/2004
DIGITALIS GLYCOSIDES	2	02/12/2004
POTASSIUM SUPP./CHLORIDES	2	02/01/2004
AMLODIPINE/NORVASC	1	01/25/2004
POTASSIUM SPARING DIURETICS	1	01/14/2004

Providers Seen

Provider name	Specialty	Phone #	Last service date
WENDELL VENDETTI	CARDIOLOGY	610-249-5587	09/06/2004
DEWITT EPPES	FAMILY PRACTICE	610-296-8200	07/31/2004
LAWRENCE URBINA	EMERGENCY MEDICINE	610-723 -4452	04/17/2004
KASEY CLONINGER	INTERNAL MEDICINE	215-828-1960	04/01/2004
SPARKLE YANEY	OTHER	610-443-1205	02/22/2004

Report generated on: 01/28/2005
Information provided by: MCO 1
Report based on services provided as of: 12/31/2004
Name: BRACERO, DEANGELO
DOB: 01/01/1957

ID: JM1QBZJ1H00
Gender: M

Eligibility: 01/01/2000 - 01/01/2006

Early Detection Flags

- RENAL FAILURE OF LOW SEVERITY

Treatment Opportunities

- DIABETIC and NO EYE EXAM IN 12 MONTHS
- RENAL FAILURE WITH ANEMIA AND NO EPOETIN USE

Information provided by: MCO 1

MEDecision

PATIENT CLINICAL SUMMARY

TERMS AND CONDITIONS FOR SECURITY AND CONFIDENTIALITY OF PATIENT RECORDS AND INFORMATION

1 General. An authorized provider ("Provider" or "You") are permitted to access certain patient care information for patients whom Provider treats in connection with Payer's care management program. Payer maintains confidential patient records and information that can be accessed through the Patient Clinical Summary software tools ("PCS System"). The PCS System is licensed to Payer by MEDecision, Inc. ("MEDecision") pursuant to a licensing agreement ("License Agreement"). MEDecision shall have the same rights against any Provider using the PCS System as it has against Payer under the License Agreement. Provider is placed in a unique position of trust since a major responsibility of Provider is the security and confidentiality of patient records and information. Security and confidentiality concern all providers who have access to confidential patient information. The purpose of these terms and conditions ("Terms and Conditions") is to clarify the Provider's responsibilities when utilizing the PCS System in connection with Payer's care management program. By accessing and utilizing this information, you agree to the Terms and Conditions of this agreement ("Agreement"). If you do not agree with these Terms and Conditions or you have inadvertently accessed this information, you should immediately cease using this information.

2. Scope of Use. Subject to the terms of this Agreement and for the sole purpose of assisting in the evaluation and treatment of patients, Provider is permitted to access and use the PCS System. Provider may use the PCS System and Confidential Patient Information (defined below) made available thereunder only upon patient consent and as authorized or required by applicable federal and state law, including, without limitation, the privacy and security regulations promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). You should refer to Payer's Privacy Policy for limitations on your right to use and disclose Confidential Patient Information in connection with Payer's care management program and to determine if a use or disclosure of such Confidential Health Information is otherwise permitted hereunder. You agree you have read and understand Payer's Privacy Policy. Use of Confidential Patient Information is permitted only for Provider's internal use on the PCS System in the ordinary course of business in connection with Payer's care management program, and such Confidential Patient Information shall not be used directly or indirectly on behalf of any other party. Further, notwithstanding anything to the contrary in these Terms and Conditions, Provider may not (a) use or otherwise disclose Confidential Patient Information for any other purpose other than a purpose expressly stated in these Terms and Conditions; or (b) use or disclose Confidential Patient Information in the manner that violates or would violate applicable federal or state law. Within these parameters, Providers may use Confidential Patient Information for, in, and on a single computer unit used by Provider (the "Work Station")

3 Security Key. Provider may activate and use the PCS System provided that Provider is a participating provider of Payer and has been issued an appropriate access code and password. Provider shall keep such access code and password secure from unauthorized access by and disclosure to any third party.

4. Confidentiality. In general, Provider must treat all patient records, materials, information and Protected Health Information ("PHI") accessed on or through the PCS System as confidential (collectively, "Confidential Patient Information"), and not use or disclose such Confidential Patient Information except as permitted hereunder. PHI means individually identifiable health information that is transmitted electronically or maintained in electronic or other medium. The term "individually identifiable health information" means health information, including demographic information collected from an individual that: (i) is created or received by a health care provider, health plan, employer or health care clearinghouse, and (ii) relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present or future payment for the provision of health care to an individual, and (a) identifies the individual; or (b) creates a reasonable basis to believe the information can be used to identify the individual. The term "health information" means any form of oral or written information that: (i) is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse, and (ii) relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual. Provider shall not, for any reason, either directly or indirectly, divulge any Confidential Patient Information to any third party or use such Confidential Patient Information for Provider's own benefit.

5 Expressly Prohibited Uses. Provider agrees that Provider (a) shall not make or permit unauthorized use or disclosure of any Confidential Patient Information maintained or stored on the PCS System or accessed by Provider through the PCS System, (b) shall not seek personal benefit or allow others to benefit personally by knowledge of any Confidential Patient Information which has come to him by virtue of his access to the PCS System, (c) shall not exhibit or divulge the contents of any record or report a false, inaccurate, or misleading entry, nor shall Provider knowingly expunge or cause to be expunged in any record or report a data entry; (d) shall not remove any official record or report or copy thereof from where it is maintained, (e) shall not aid, abet nor act in conspiracy with another to violate any part of these Terms and Conditions; (f) make unauthorized use or disclosure of the Confidential Patient Information; (g) disassemble, decompile, recast, or reverse engineer the PCS System or create a substantially

similar system; (h) distribute any Confidential Patient Information for commercial gain or otherwise; (e) copy the Confidential Patient Information in any form except as necessary to use such Confidential Patient Information in accordance with this Agreement; or (f) modify, alter, delete or obscure any Confidential Patient Information. Provider shall ensure his compliance with this Agreement and shall bear the responsibility for any breach of this Agreement by him. Any knowledge of a violation of these Terms and Conditions shall immediately be reported to Payer. If Provider breaches any of the Terms or Conditions of this Agreement, Provider's access to this information shall be terminated immediately. Violation of these Terms and Conditions may also lead to reprimand; suspension or termination of Provider from Payer, consistent with Payer's credentialing policies.

6 Authorization for Use Compliance Verification. Provider expressly authorizes Payer to electronically access, from time to time, the Work Station to verify Provider's compliance with Section 2 hereof. In connection with such access, Payer shall have the right to verify: (a) the name of Provider; (b) the name of Provider's registered user number; (c) the internet address of the Work Station, and (d) the name of the registered user on the network.

7. Warranty Disclaimer. PROVIDER UNDERSTANDS AND AGREES THAT (A) ANY INFORMATION MADE AVAILABLE IS PROVIDED TO PROVIDER "AS IS" AND (B) MEDECISION AND PAYER EXPRESSLY DISCLAIM, ANY AND ALL REPRESENTATIONS AND WARRANTIES, WHETHER EXPRESS OR IMPLIED, WHETHER ARISING BY STATUTE, COURSE OF DEALING, USAGE, OR TRADE, INCLUDING BUT NOT LIMITED TO ANY WARRANTY OF ACCURACY, COMPLETENESS, PERFORMANCE, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT OR TITLE

8. Limitation of Liability. UNDER NO CIRCUMSTANCES WILL MEDECISION OR THE PAYER BE LIABLE FOR ANY INCIDENTAL, SPECIAL, PUNITIVE OR CONSEQUENTIAL DAMAGES ARISING OUT OF OR IN CONNECTION WITH THIS INFORMATION MEDECISION'S AND PAYOR'S LIABILITY FOR ANY CAUSE OF ACTION ARISING UNDER OR IN CONNECTION WITH THIS INFORMATION OR OTHERWISE (WHETHER ARISING IN TORT, CONTRACT OR OTHERWISE) WILL BE LIMITED TO THE AMOUNT OF LICENSE FEES RECEIVED BY MEDECISION UNDER THE LICENSE AGREEMENT

9. Patient Care Responsibility. Provider acknowledges and agrees that MEDecision is not engaged in the rendering of medical, health or psychological diagnosis, treatment, evaluation, patient care or any other kind of personal professional services in licensing the PCS System to Payer. The PCS System and the information to be made available are to be used as a tool to assist Provider in connection with Payer's care management program. MEDecision expressly disclaims all responsibility for any liability, loss or risk which is incurred as a consequence, directly or indirectly, of Payer's use of the PCS System.

10. Indemnification. Provider hereby agrees, at Provider's own expense, to indemnify, defend and hold harmless MEDecision and Payer from and against any loss, cost, damages, liability, or expense arising out of or relating to (a) a breach by Provider of the Terms and Conditions of this Agreement, or (b) any violation of any law, regulation or rights of a third party.

11. Miscellaneous. Neither party shall be responsible for any delay or failure of performance resulting from causes beyond its control. This Agreement may be modified and updated from time to time and Provider will be informed of such changes. This Agreement is governed by Pennsylvania law. Provider consents to jurisdiction of the courts in Pennsylvania. Provider may not assign this Agreement. Any noun or pronoun used in this Agreement shall be construed in masculine, feminine or neuter as its sense and use may require.

12. Survival. The provisions of Sections 4, 7, 8, 9, 10, 11, and this Section 12 shall survive termination of this Agreement.

By accessing this information, you represent that you have the authority to do so and acknowledge and agree that you have received a copy of, have read, do understand, and will comply with these Terms and Conditions for Security and Confidentiality of Patient Records and Information.

Appendix B. HCFA Uniform Bill-92 (UB-92) codes and Current Procedural Terminology (CPT) codes used for identification of select component resources

Service Category	CPT	UB92
Pharmacy		250-269
Laboratory	80048-89240	300-319
Diagnostic radiology	70010-76499, 76506-76999, 78000-78999	320-329, 340-341, 349, 350-359, 400-409, 482, 483, 610-619, 730-739, 920, 929
CT scans	70450-70498, 71250-71275, 72125-72133, 72191-72194, 73200-73206, 73700-73706, 74150-74175, 75635	350-359
MRI scans	70540-70559, 71550-71555, 72141-72190, 72195-72198, 73218-73225, 73718-73725, 74181-74185, 75552-75556	610-619
Medicine-Cardiovascular	93501-93581, 92950-92998	480-481, 489
Surgery/OR/recovery charges	10021-32999, 33010-37799, 38100-69979	360-369, 490-499, 710-711
Medical-Surgical Supplies		270-279, 620-624
Room & Board		100-169
ICU & CCU		200-219
ED (facility)		450-459
ED professional fees and E/M	99281-99285, 99288	981
Professional fees (non-ED) and E/M	99201-99275, 99289-99499	960-969, 970-979, 982-989

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