Public Written Comments Submitted to PCAST
from December 23, 2010 to February 22, 2011 (starting on page 2).

Oral Public Comment Submitted to PCAST
Written statements were not provided for the oral public comments given to the PCAST during the March 2011 meeting. To view oral comments please visit the video webcast at http://www.whitehouse.gov/administration/eop/ostp/pcast

As specified in the Federal Register Notice, because PCAST operates under the Federal Advisory Committee Act (FACA), all public comments and/or presentations will be treated as public documents and will be made available for public inspection, including being posted on the PCAST Web site.
Public Written Comments Submitted to PCAST

from December 23, 2010 to February 22, 2011
With all your respect, kindly to find enclosed a short impression of our Center, Yemeni Center for Diplomatic Studies & International Relations; YCDSIR

Looking forward for the growing of this cooperation subject.

Warm wishes,
Sincerely,

Fouad ALGhaffari
Advisor - Member of Executives
Yemeni Center for Diplomatic Studies & International Relations

Attachments:

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A number of significant international changes and variables took place between the capitalistic and socialistic blocs were the highlights and pinnacle events during the nineties of the last century. By the end of the Cold War between the two blocs, which started by the end of World War II in April 1945, and the establishment of the United Nations in October the same year, the result of these developments was the collapse of the Soviet Union and the dissolution of the Socialist system entirely, whereby, it was transformed from the exhaustive Communistic to the Capitalistic Democratic and liberal system. It is arguably that such tremendous changes and variables that took place are not any less important from the events and outcomes of World War II.

However, in spite of the developments taking place at the end of the 20th century and the turn of the 21st century, the United States has remained in the lead although it has undergone a great economical loss as a result of the global financial recession and other crisis and catastrophes including the informational shock initiated by Wikileaks, which revealed more than 250,000 top secret documents in November 2010. The US has also received a painful blow when a tiny desert country like Qatar beat it and succeeded to host the FIFA World Cup in 2022. Undoubtedly, Qatar’s achievement is a gain for all Arabs and it is a precursor of the recession of the absolute dominance of the super powers. As the success of the state of Qatar was extraordinary, At the same time it happened that the Gulf Cup 20th, hosted by Yemen, was successful and for the good results, number of Gulf investors indicated their willingness to engage in investment projects in different fields, particularly in tourism and industries at Aden province. At this stage the Republic of Yemen is proud that it has achieved political victories and proved the success of the Gulf Cup 20th, the Gulf media expressed their views that Gulf Cup 20th in Yemen was the most successful session of the GCC in the history of Gulf sports.
In spite of all these obstacles, the USA overwhelmingly dominates the place of pride and it may continue to dominate the scene for the coming three or four decades. However, America will not be alone as is the case today. It will rather bear the consequences of its oppression policy. Unfortunately, USA due its policies has been exposed to terrorism act which has been denounced by different countries of the world, on its home soil on 11th September 2001, when massive terrorist acts hit New York and Washington D.C.

without any calculation to the results and outcomes, the USA went to invade Afghanistan in hope of pursuing and chasing after the Taliban government and in an attempt to evict them from the Capital, Kabul and push them out towards the Tora Bora Mountains. Not only Bush the son generated unfair response globally and disgraced the reputation of its possession of weapons of mass destruction. Unfortunately, USA has learnt a valuable lesson from this incident, how-ever, Yemen is still the only trapped victim of those aiming to defame its reputation in order to remain captive of a number of challenges and dilemmas, primarily, poverty which leads to unemployment and an increase in the population and a reduction in the Gross Domestic Product and shortage in the national food security. For example, the international re-search centers have indicated in their forecasts, a shortage in drinking water in Capital Sana’a by the year 2050 and maybe earlier, this could also be contribution to the cultivation of the Qat plant that dominates the agricultural sector for the Yemeni farmers and requires an extensive amount of water.

In addition, the corruption in government institutions, the absence of the principle of reward and punishment and the absence of the justice that is required in its various forms in the Civil society organizations and entities, are all significant challenges that should be eliminated from our society. In fact, Yemen is not the only country that suffers from terrorism but it was affected even more due to its strategic position. Unfortunately, the bombarded parcels incident by the end of October, 2010 triggered unfair response globally and disgraced the reputation of Yemen. Such incident might have pleased some countries that do not like Yemen to step out of the vicious circle it lives. This sad event has incited some countries to boycott the Yemeni official airliner for about 3 weeks after the incident.

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Finally, Obama’s administration has declared the partial withdrawal of the troops by the beginning of 2010 and passing over the security responsibility to the Iraqi troops. Incidentally, this is similar to what has happened in Afghanistan, whereby, the NATO leaders after their losses and defeats have similarly adopted, in their summit that was held between 19/20 November 2010 in Lisbon, the allies’ strategy of withdrawal of troops from Afghanistan and the actual withdrawal that will commence in 2011.

The Republic of Yemen is an integral part of the world and it controls a mouth-watering strategic position. Yemen controls the Gulf of Aden through which all the oil coming from the Gulf States passes.

Yemen does also control Bab Al-Mandab and Myoon Island on the Red Sea. Yemen has been exposed to a series of civil wars such as the war with the Houthis in the North. It has also been exposed to a number of terrorist attacks by Al-Qa- da, led by the late Osama Bin Laden. In fact, Yemen is not the only country that suffers from terrorism but it was affected even more due to its strategic position. Unfortunately, the bombarded parcels incident by the end of October, 2010 triggered unfair response globally and disgraced the reputation of Yemen. Such incident might have pleased some countries that do not like Yemen to step out of the vicious circle it lives. This sad event has incited some countries to boycott the Yemeni official airliner for about 3 weeks after the incident.

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God Willing, and through the efforts of the leaders of this centre, the Yemeni Centre for Diplomatic Studies & International Relations aims to create an ideology that is based on understanding the history of each event, comparing, analyzing, crystallizing and forecasting events before occurring. This will be done in while into account the following two dimensions; proposing and presenting the tactical and strategic alternatives that serves the nation while adhering to the Yemeni political direction; Conforming with the latest diplomatic requirements and applying the principles of common mutual benefits between nations that are constantly evolving in a world of international changes.

The President / Founder of Yemeni Centre for Diplomatic Studies & International Relations spent most of his working years in the Ministry of Foreign Affairs. However, the time came for him to retire from the official scene and follow his deep aspirations and ambition, which were clearly evident in his academic research, lectures, and publication. His many years of experience in an honest, truthful, impartial and professional manner, and stimulating progress in all facets of activities and actions that are in harmony with the policy of the Center. On top of those issues are the central and the long-awaited issue of Arab unity. It is hoped that such free Arab ideas will create a new phase with an aim to liberating the Arab citizens from the Ocean to the Gulf.

In our opinion, the Arab leaders must work on fulfilling the demands of the Arab congregations in urging the Arab research institutions and those responsible for the Arab culture and ideologies in drafting the proposal for a united Arab nation. In this context, the Centre urges all government institutions that are affiliated with the regional and international Centres to participate and share their opinions, through an exchange of knowledge, as well as, scientific and cultural information. In this regard, the Yemeni Republic has preceded many other nations in submitting a proposal for establishing a United Arab nation, which was discussed in Sert Summit in October 2010. Previously, the president of the Centre for Diplomatic Studies & International Relations has published the Yemeni proposal in his book; “Snapshots on the Yemeni unity across history”, which was published in 2004, and the Centre is determined on presenting studies that are related to economic and political coalitions on all local, regional and international fronts and in different fields that serves the Arab and Islamic states.

In addition, the centre aims to strengthen its cooperation with the national local administration, as well as, other Arab research Centers in matters of interests covered in the Arab, Islamic, Asian, African and International front. The centre will also present studies on the United Nations and its various regional organizations, the Arab League, as well as, the noble objective of utilizing the Arab league as the central driving force between the Arab leaders, the European Union, the regional Arab councils, and the civil society organization. The civil society play a pivotal role in assisting the central and the long-awaited issue of Arab unity, although the Center received the official license from the authorities, the Center already started exercising its mission from the beginning of this Year 2011. For all of that, the Centre hereby invites the leaders of Arabic and Yemeni political parties to participate in the establishment of the Center with government, while adhering to the existing laws, constitution and its correlation to a healthy democratic environment; and finally, how the democratic climate becomes the mechanism for resolving conflicts and disputes between political and ruling parties.

For the above reasons the idea of establishing the Yemeni Centre for Diplomatic Studies & International Relations was conceived!
Establishment

YCDSIR was founded in December 2010 pursuant to the approval of H. E. the Minister of Foreign Affairs, Note No. 1 / 1 / 130 / 1700, on 11 / 12 / 2010. Thereupon, Ministry of Social Affairs & Labor through the Social Development Sector at the General Department of Associations & Unions, issued the License No. ( 458 ) on 21 / 12 / 2010, for the establishment and practicing activities.

YCDSIR is a scientific, cultural, social and advisory center, within the civil society organizations. Thus, it is a national non-governmental entity of autonomous financial liability under the control of its president. It was established in accordance with provisions of the National Associations & Institutions Law No. (1) of 2001 and its Executive Regulations issued by the Prime Minister’s Decree No. (129) of 2004.

The Mission of the Centre

The Yemeni Centre for Diplomatic Studies & International Relations aims to define the depth of the Yemeni role that has been historically instrumental on both the national, Islamic and humanitarian level. In addition, the centre aims to revive the Arab and Islamic unity concepts and also define the capabilities of the Arab and Islamic nation in spite of the various challenges they face due to their unique geographic positioning, as well as, their rich wealth of resources. The centre will also focus on the unique importance of the Holy Islamic sites in Jerusalem, Mekkah and El Medina.

The centre aims to become the pillar for information prosperity and offering such information to decision makers. However, the centre will not be able to meet its obligations and achieve its mission without the ongoing cooperation, financial and moral support of all concerned parties; the government sector; and the private corporation. The centre aims to perform the following:

- Analyze, crystallize, evaluate, source information that impacts Internal and foreign policies of Yemen and the Arab world, as well as, to depict the different scenarios to be implemented according to the local, regional and international variables.
- Commit in cooperating with the official entities, such as; the Yemeni Ministry of Foreign affairs; the diplomatic institution affiliated with of the Ministry of Foreign Affairs; the Yemeni Universities; the regional Arab Diplomatic institutions and civil society organizations; the Yemeni and Arab Centre of studies that is affiliated with the activities of the Centre; and finally, the regional and international organizations that have similar objectives and missions.
- Assist in strengthening the future vision and holistic view when it comes to local, regional and international obstacles, dilemmas and situations, as well as, defending issues of national, Islamic and humanitarian importance.
- Offer studies on the following; the future of the peace process in the middle East through direct and indirect negotiations with the Israeli government; the Arab peace initiative; the United Nations resolutions on the Israeli and Arab struggle since the founding of Israel in May 1948; and finally the Security Council resolutions on the withdrawal of Israel from all Arab occupied territories in 1967.
- Crystallize the culture of dialogue, negotiation, and peace settlement for all disputes in light of the group of international crisis and according to the International laws.
- Emphasize the importance of the Arab Social and economic sustainable development that aims to establish a social welfare for all Arab citizens in an environment that is peaceful and stable.
- Emphasize the role of political organizations and parties in strengthening peace and stability.
- Acknowledge the importance of respecting human rights and the supremacy of law when it comes to maintaining peace and stability.
- Spread the concept of gender equality and enable women to become an effective participant in serving society.
- Offer political consultations and recommendations on the Arab-Arab relations; the Arab solidarity that is stipulated in the Arab league Charter; the common defense strategy; and finally, the bilateral agreements between Arab states.
- Organize hosting discussion group meetings; seminars; workshops; and study groups to improve the knowledge awareness about strategic and diplomatic facets
- Organize study group and focused lectures on the Yemeni role in spreading Islam; the importance of preserving the Yemeni unity; and its achievements in order to achieve the aspire Arab unity through the cooperation with similar Arab and Yemeni Institutions.
- Present studies on diplomatic skills development; the art of protocol and etiquette; preparing regular publications on the above issues; and also translating publications of such issues from other languages to Arabic.
- Present independent studies on development phenomena in each and every Arab nation.
- Present studies and lectures on the relationship between Yemen and the rest of the world, especially with the states of the Cooperation Council for the Arab states of the Gulf; the Sana’a Cooperation grouping; and finally, the rest of the African horn states.
- Welcome the participation of Arab ambassadors and foreigners living in our country in order to facilitate the exchange of thoughts and ideas on the local and Arab issues on multiple levels.
- Invite their Excellencies, the Arab and foreign ambassadors in our country as honorary guests, and preset to them specific lectures.
- Organizing an annual conference that reflects the latest developments and achievements of the Centre that took place during the year. This will be achieved via hosting a number of lectures; seminars; and discussing the publications that were published.

**Importance of the Centre**

The importance of the Yemeni Centre for Diplomatic studies & International Relations stems from the following the accelerated pace of development that is imposed by globalization policy in all aspects of life. The tangible changes in the political, economic, security, cultural and humanitarian facets of life in the Arab region, and the world generally, as well as, the specific transformation that took place by the end of the Cold War and the possibility of its re-emergence again, have all imposed more pressure on governments and national institutions, including the political, economic and military coalitions to focus and pay attention to the research Centers, especially, those centers that focus on research forecasting, information authenticity.

We have diligently worked on establishing this Centre to assist in finding an effective tool that constantly offers information in different format and structure at the right time to assist decision makers in performing their tasks and duties in order to achieve results for matters of national interests.

**General Policy**

The Centre aims to fulfill its obligations according to its aspiration whereby, together with other research Centers; it aims to clarify the objectives and political, social and cultural dimension in the Yemeni society. This will be achieved through, offering related studies and researches concerning basic human rights which are listed and specified in the Islamic religion; the International declaration for human rights; the Yemeni constitution. Thus, the centre aims to stimulate the spreading of culture of political and diplomatic skills between individuals and groups with all efficiency and effectiveness and according to the latest diplomatic requirements. This will include personal relationships between leaders and officials which has a pivotal impact on the advancement of relations between nations.

Therefore, it is clear that when such humble objectives are met and where peace prevails between members in society and between leaders, politicians and university professors, the Centre will be able to analyze; crystalize; source information about issues of importance for decision makers and foreign policies; and finally, propose and evaluate strategic alternatives that serves the interests of the both the Arab and Islamic states while adhering to the interests of the state.
Objectives

- As it was mentioned above, one of the main objectives of the Centre is to publish studies; academic researches; articles related to diplomacy and related international relations; resolves crisis and international problems through the ideologies that foster the attainment of peace, while focusing on presenting studies about the Arab and international political and economic coalitions, and finally, the importance of activating the role of the Arab cooperative work through the regional coalitions in order to achieve a United Arab nation.

- Publishing knowledge around the latest principles of diplomacy and international relations; updating and organizing the exchange of information through publishing studies that focuses on issues of international and chronic crisis; listing the available mechanisms to find suitable solutions, such as dialogue; direct; and indirect negotiations that serve the interests of political sciences and politicians.

- Participate in organizing seminars; study forums; conferences in the field of strategy, diplomacy and international relations and other topics that are related to the activities of the centre; inviting the political parties and political organizations to participate in the effective and constructive dialogue according to the national constants.

- Offering consultations to the government entities and other concerned entities which helps improve their official mandate.

- Establishing a private printed library and an electronic library on the World Wide Web which focuses on books and articles related to the topics of diplomacy, International relations and strategy.

The Center's Structural Organization

- **Honorary President**: Dr. Abu-Bakr Abdullah Al-Qirbi
- **Executive President / Chairman of Board of Trustees**: Ambassador / Dr. Ali AbdulQawi ALGhaffari.
- **Board of Trustees** consists of the figures of those devoted in the internal and external policies of the Republic of Yemen. It also includes in its membership distinguished elites of politicians, diplomats, economists, academics and persons of wide expertise in the Center’s fields of interest.

- The Board of Trustees undertakes the strategic plans for the Center’s and supervise its executive management and interrelationship with the various ministries, governmental and private bodies and civil society organizations inside the country, and follow-up and monitor its foreign relations.

- **Board of Directors Consists of the Executive Board as follows**
  - Ambassador / Dr. Ali AbdulQawi ALGhaffari (President)
  - Prof. Dr / Mohammed Mohammed Mutahar (Member)
  - Ambassador / Dr. Hameed Mohammed Mutee Al-Awadhi (Member)
  - Mr. Fouad Ali ALGhaffari – Advisor (Member)
The Center’s Sections

- Foreign Affairs
- Public Affairs
- Financial & Administrative Affairs
- Secretariat
- Studies & Researches
- Website – Eng.

The Center’s Financial Position

The Center’s financial resources depend on members subscriptions and unconditional donations and endowments from bodies, institutions and organizations in a manner that would not contradict with the Center’s Articles of Association and the applicable laws and regulations in the country.

The Center’s capital is one million Yemeni Ryals (YR 1,000,000) at the Yemen Kuwait Bank for trade & Investment under account number, YR: 402,113,8445, $: 402,103,12163.

Enrollment

Membership enrollment is the sum of (50,000 YR) once per year. There will be a schedule and meetings with the members.

For the supporting and financing sponsors, brief introductory information will be issued in the Center’s publications and website.

Curriculum Vitae

H.E Ambassador DR. Ali AbdulQawi AlGhaffari

President of Yemeni Diplomatic Center for Diplomatic Studies & International Relations (YCDISR)

- Born 1950, Haryah Village, Al-Naderah City, Ebb province.
- He was among the first batch of teachers 1967 - 1968.
- Joined the 70-day war among members of the people’s Resistance 1967 - 1968.

Qualifications:
- Diploma, Higher Studies in International politics, New York University.
- MPhil, political Science, Baghdad University / 1996.
- He speaks English, Czech and Arabic languages.

Portfolios:
- Worked in various department of the MFA.
- Director, Personnel Department.
- Director, Research, Training and Planning Department.
- Participated in a number of international conferences.
- Posted to a number of the Yemeni Diplomatic Missions / some at which he was the Charge d’Affaires.
- Assistant professor at the political Science – at Sana’a University / 1996 - 1999.

His Work:
- Diplomacy of Loyalty / April 2006.
- Visions on the nationally revolution, unity and joint Arab action - Sana’a / 2009.
- Book on Foreign policy of the Republic of Yemen “under Printing”.
- He Wrote many articles, and researches and presented many lectures, local & abroad

14 YEMENI CENTER For DIPLOMATIC STUDIES & INTERNATIONAL RELATIONS

15
From:  "Tim Williamson" <globaleconomy101@gmail.com>
Subject: Building the correct foundation for STEM in America
Date: Wed, February 9, 2011 3:17 pm
To:  "House education committee" <jimmy.hopper@mail.house.gov>, "U.S. Metric Association" <usma@colostate.edu>
Cc:  "House Committee on Science" <zachary.kurz@mail.house.gov>

Congressmen, Senators, Committee Chairman, Members, staff:

Here is something that is directly related to the success of the USA, and is the foundation of all trade, science, technology, engineering and math (STEM) - implement SI metric across the country. Take away the voluntary provisions in the old metrification law. Our refusal to implement SI metric is costing us billions in lost trade and in missed opportunities for STEM innovations in new technologies and new industries on which the future of the US is dependent.

We also need the committee's help at Metric America Foundation<http://metricamerica.blogspot.com/>for funding to purchase four (4) 'metric only' kits per school for use in our K - 12 schools. There are 130,000 schools across the country. That means that we need 520,000 kits at $280.00 per kit. The total cost is $145,600,000.00 USD. This is a very small price to pay to help our children become the highly trained and highly skilled, creative and innovative workforce of tomorrow. This is a very small price to pay to help restore our nations competitive advantage in our global marketplace of trade, science, innovation, and new technologies. Businesses, individuals, and other civic organizations are being asked to support this effort as well.

Will you help restore American greatness? Will you help restore American pride by your commitment to this endeavor?

Giving our children this one advantage by having these 'metric only' kits in their classrooms, by removing another hurdle and obstacle to their success by not knowing the metric system, is in best interest of our great nation.

Thanks!

Tim Williamson

http://metricamerica.blogspot.com

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From: agvette5@aol.com <agvette5@aol.com>
To: Stine, Deborah D.
Sent: Sat Feb 12 14:41:14 2011
Subject: Request phone conference: Obama’s people need to know about this

Ms. Stine,

Apologize that I missed your call this week. I trust you got to read original e-mail documenting massive increases in billings/overcharges with the advent of EHR (I will send again in case you don't have it). In a second e-mail I will send part of the voluminous literature documenting concern about EHR fraud. I am assembling a cadre of academic physicians including Dr. Silverstein @ Drexel and Dr. Stafford @ Stanford and Dr. Simborg who chaired the 2005 and 2007 commisions studying EHR fraud. All have published voluminously on Hazards and possible fraud/abuse/waste associated with EHR. They are very interested in my data and we wish to get it in front of people who can do something about it (deserves congressional testimony). Right now the Republicans interested in repealing EHR funding seem very interested and I'm afraid they may try and spring a trap on the Administration. [I'm a huge Obama supporter].

I am free all day Monday and Tuesday. See below the original e-mail. Thank you, Al Gravett MD MPH FACEP

45 Billion yearly in medical overcharges with Electronic Health Records [EHR] (in ER’s alone)

Attached are graphs/papers showing the following 1) Massive increase in upper level (4 and 5) billings 2002-2008 in ER's with advent of EHR (part of this is "paper template" charting which is essentially the same thing) 2) Absolute increase in Medicare/Medicaid payments to ER doctors due to this phenomenon 2002-2008 (2 billion @ 80% allowed Medicare rate or 2.6 Billion). Hospitals charge their "hospital component" based on ER doctor billings thus at least doubling the direct Medicare/ Medicaid overpayments to 4-5 Billion. HOWEVER, hospitals and doctors actually charge about 4 times what Medicare allows thus total overcharges to Medicare/ Medicaid patients is about 20 Billion (3rd graph). Because Medicare/ Medicaid is only about 45% of the payer mix, 55% of the population receives the full inflated bills adding another 24.5 Billion. Thus roughly 45 Billion in total overcharge to the system is occurring due to EHR's, an enormous burden on taxpayers and American Consumers. There is additional overcharging occurring in other sectors of medicine due to EHR but ER is by far the worst offender. Papers 4 and 5 are 2004 and 2006 studies warning of the upcoding problem and are the source of the 2002 numbers.

I implore you to disseminate this information. This needs to be fixed before things get worse by using Stimulus money to pay for computer programs that do nothing but jack up patients bills. America needs good HIT, we just don't need this current generation of EHR which grossly
upcode. I have a very large collection of information on this issue and am ready to go public to stop this widespread abuse of the system (if not outright fraud).

Regards,

Alan Gravett MD MPH FACEP

309-824-0990

From: agvette5@aol.com <agvette5@aol.com>
To: Stine, Deborah D.
Sent: Sat Feb 12 14:43:54 2011
Subject: Fwd: supportive papers for EHR fraud

Copy of articles sent to one of the CMS people I'm working with. See explanations below. Al

-----Original Message-----
From: agvette5@aol.com
To: joel.truman@cms.hhs.gov
Sent: Thu, Feb 10, 2011 12:56 pm
Subject: supportive papers for EHR fraud

1) Tough read but look at sections headings. Credible professional organization (Billing coders) accusing the whole CCHIT (certifiers of health info systems) system of producing fraudulent codes and data.

2) Nice Medical Economic article that outlines the whole problem of EHR's and the government stimulus program. (additional info available from small text boxes by going to Medical economics site and looking at back issues for this date).

3) Written by Dr. Simborg who chaired 2005 and 2007 committees looking at HIT and fraud. Asks question if all these computer programs do is upcode then why are we promoting them?

4) Nice recent article outlining that unless you really try and follow specific guidelines (which don't work clinically according to Simborg) you will be upcoding with EHR's

5) Another Simborg article documenting his frustrating experience with the national commissions on HIT and pointing out that if nothing was done the problem will get worse (it has).

Next up....specific McKesson related evidence (will have by AM). Al
Ineffective policies from numerous key organizations have contributed to widespread EHR compliance problems.

Well-intended physicians are being victimized when audits reveal their EHRs have allowed non-compliant claims.

Audited practices have been fined between $50,000 and $175,000 per physician for their inadvertent infractions.

Today's political and economic environment has focused a spotlight on healthcare reform and the promotion of health information technology in particular. The Obama administration has promised to invest $10 billion per year over the next five years on HIT, including electronic health records. Senator Max Baucus, chairman of the Senate Finance Committee, says HIT represents "the beginning of healthcare reform and a key part of the economic recovery."

The Centers for Medicare & Medicaid Services (CMS) is also exerting increasing pressure on physicians to purchase HIT: financial incentives for using electronic prescribing through 2013 and rising penalties to practices that fail to employ this technology starting in 2012. The administration's stimulus package provides incentives for implementing and using certified EHR systems, while those practices that don’t adopt these systems by 2014 will receive reductions in reimbursement.

Health policy advocates justifiably point to a myriad of potential benefits that should result from the widespread implementation of EHRs, from safe storage of health information to electronic sharing of clinical information. The knowledge shared through this access to patients' medical data promises to improve patient safety and reduce costs associated with duplicate and/or unnecessary tests and treatments. Electronic prescribing further promises to reduce medication errors, ranging from drug interactions to misinterpreted handwriting.

Most physicians who introduce EHR systems into their practices seek promised advantages for enhancing quality care and patient safety through the systems' touted data storage and retrieval characteristics. Electronic records offer immediate access to patients' documents and data. Likewise, most physicians include among their highest priorities the goal of compliant evaluation and management (E/M) coding. Physicians believe they have a right to expect that these sophisticated and costly systems will ensure that they achieve compliant documentation and coding, thereby "making any E/M problems go away."

However, something has gone awry to create an environment that leaves well-intended physicians victimized when government audits reveal their software systems have allowed—even facilitated—submission of non-compliant and potentially fraudulent claims for E/M services. In the midst of increasing storm warnings of non-compliant designs, physicians are increasingly vulnerable to severe financial penalties.
This devastating storm has been developing for many years, often bolstered by an unintended lack of effective policies from several organizations that should have the best interests of physicians, patients, and the healthcare system at their core—organizations such as CMS, the Certification Commission for Healthcare Information Technology (CCHIT), and the U.S. Department of Health and Human Services (HHS), as well as EHR software vendors and physician training institutions (for more information).

The problem with EHRs and coding

Apr 3, 2009
By: Deborah Grid, CPC, Robin Linker, CPC, Susan Thurston, CPC, Stephen Levinson, MD

Medical Economics

GATHERING STORM CLOUDS

Analyses of problems with EHR systems by physicians and their practice managers consistently reveal that the overwhelming preponderance of their challenges relate to the rarely discussed data-entry characteristics of the electronic history and physical (H&P), not to the heralded data-storage and retrieval features of their systems. One physician personally reported that "The software forces me to enter clinical information in a preloaded format; when I see a patient three weeks later, I cannot find any individualized details of the previous visit or understand why I did what I did."

In April 2008, a study published in the New England Journal of Medicine reported similar problems, pointing out that "Notes that are meant to be focused and selective have become voluminous and templated, distracting from the key cognitive work of providing care. Such charts may satisfy the demands of third-party payers, but they are the product of a word processor, not of physicians' thoughtful review and analysis. They may be 'efficient' for the purpose of documentation but not for creative clinical thinking."

The study also reported an example of the consequences of these problems: "A colleague at a major cancer center that recently switched to electronic medical records said that chart review during rounds has become nearly worthless. He bemoaned the vain search through meaningless repetition in multiple notes for the single line that represented a new development ... Ironically, he has started to handwrite a list of new developments on index cards so that he can refer to them at the bedside."

Too often, these problems have proven insurmountable. At the Second HIT Summit in 2005, Mark McClellan, MD (then the administrator of CMS), reported "40 percent of attempted implementations fail." According to the April 1, 2006, issue of CIO Magazine, "The [Health and Human Services] department itself has acknowledged that the failure rate for EHR system implementation is 30 percent to 50 percent. Some healthcare network providers claim it is as high as 70 percent."
These electronic H&P challenges can manifest in one or more of four interrelated areas:

1. Integrity of the clinical information recorded

2. Usability, quality of the clinical care and workflow guided by the record

3. Malpractice protection

4. Evaluation and management (E/M) compliance.

When audits reveal lack of compliant documentation generated by physicians using an electronic H&P, the findings can be viewed as the “canary in the coal mine” to warn of additional impending dangers related to data integrity, quality of care, and malpractice protection.

During the last several years, a significant number of articles have pointed out compliance problems intrinsic to the majority of current EHR systems. Chief among these relate to coding engines that fail to consider medical necessity, which CMS describes as “the overarching criterion for payment,” and certain types of data-entry functionality that result in “cloned documentation,” in which the records of every visit read almost word-for-word the same except for minor variations confined almost exclusively to the chief complaint.

Physicians have long been counseled that a well-documented medical record provides the best defense in the event of a claim of medical liability. The June 2008 issue of the Journal of AHIMA quoted EHR legal expert Patricia Trites on the potential danger of electronic systems that permit copying of near-identical documentation into large numbers of patient records: "From a medical-legal standpoint, what would [lawyers] do when they [see] this chart?" she asks. "They are going to rip it apart."

In 2007, HHS and the Office of the National Coordinator for Health Information Technology (ONCHIT) published an extensive report on “Recommended requirements for enhancing data quality in electronic health record systems.” The section that reviews E/M documentation features (and analyzes current certification criteria for these EHR features) advises that "EHRs provide a variety of tools that enable a provider to be more efficient when documenting an encounter . . . These tools include the use of defaults, templates, copying, and others. The report then continues with the warning: "[These tools] can be extremely helpful if used correctly; however, the tools can also open the EHR [system] up to fraud or abuse."

The problem that physicians face is that most current EHR system designs have failed to incorporate protections to ensure the correct use of these shortcut tools. Without such "error proofing," it is not feasible for physicians, while concentrating on patient care, to differentiate the settings in which these various tools can be used compliantly from those circumstances in which their use could lead to pliant or even fraudulent documentation.

THE PERFECT STORM CONVERGES

Let's summarize. Where are the storm fronts forming this perfect storm coming from? An EHR system "weather map" reveals the following:

- Physicians whose conventional medical education lacked training in the relationship of compliance to quality care and also failed to provide medical record tools that promote compliant (and efficient) documentation and coding
- Time constraints imposed by significantly constricted reimbursement environment
- Powerful incentives for purchase and implementation of EHR systems
- Software systems that a) may have coding engines that fail to account for medical necessity; b) may have designs that automatically guide physicians to create records with high levels of documented care for every visit; c) may have shortcut documentation tools that create "automated" documents, identified by HHS as "having the potential for fraud and abuse"; and d) therefore consistently derive and recommend submission of high-level E/M codes for almost every patient encounter
- Accurate Medicare or Office of the Inspector General (OIG) auditors reviewing medical records of the practices whose recently implemented medical records have drawn their attention by consistently submitting claims for high levels of E/M care.

Ms. Grider, Ms. Linker, and Ms. Thurston are three compliance experts who were called in to assist different physician groups during federal and state audits of those groups' electronic H&P records, conducted either by individual Medicare Carriers, Recovery Audit Contractors (RACs), or the Office of the Inspector General of the HHS. In each of the four cases, the audits revealed pliant E/M claims that were submitted as a consequence of physicians using their EHRs in accord with their particular designs for E/M documentation and coding.

The four practices employed between 1 and 10 physicians. The government audit evaluated between 20 and 100 charts per physician, and the percentage of charts failing audit for each physician ranged from 20 to 95 percent.

As a result of these findings, each practice was assessed a significant penalty for pliant documentation and coding. For the practice with the lowest percentage of failed audits, the final determination required repayment to Medicare of approximately $50,000 per physician. For the other three practices, the repayments ranged from $150,000 to $175,000 per physician. For at least one of the practices, the audit also imposed an administrative requirement of prepayment review for 100 percent of all future Medicare claims.

Even though each practice was using a different EHR, there was remarkable similarity in the design and functionality limitations identified as the causes of their compliance problems:

- All of the systems had designs that failed to meet all of Current Procedural Terminology's and Documentation Guidelines for Evaluation and Management Services' published requirements for compliant documentation of medical history, physical examination, medical decision-making, and nature of the presenting problem(s) (which is the E/M system's measure of medical necessity)
- Each of the systems included three or more types of data-entry functionality that has been consistently identified as having the potential to promote non-compliant or even fraudulent documentation
- The E/M coding engines of all four systems failed to consider the three levels of risk in decision-making, failed to consider medical necessity in determining appropriate code levels, and failed to recognize the critical role of medical necessity in guiding medically indicated levels of care, documentation, and coding.

The authors who reviewed the records and audits for these practices observed that while many EHRs present one or more mechanisms to automate documentation of required history and examination elements, from both the compliance and the data-integrity perspective, automation is not documentation.
The added danger is that such automated documentation can also distort physicians' optimal care and workflow, and destroy data integrity. For example, in one of the reviewed practices, use of the EHR's preloaded macros for the physical examination actually created automatic documentation indicating that females had received prostate exams and males had negative pap smears.

The outcomes of these federal audits have been devastating, emotionally as well as financially, for the physicians and staffs of the practices involved. The failure of the EHR systems to provide for compliant E/M documentation and coding, as well as protections against overcoding and undercoding, led to statistically remarkable increases in the percentage of claims submitted with level 4 and level 5 codes. This increase drew the attention of government auditors, and the medical records created using these systems most often could neither support the levels of care submitted (primarily due to documentation shortcuts creating "cloned" records) nor the medical necessity for providing such high levels of care (due to failure to consider the nature of the presenting problem).

The overall conclusion derived from these reviews is that electronic record systems should provide sophisticated designs and functionality based on physicians' optimal patient-care workflow. They should be required not only to guide physicians in providing high-quality care and creating compliant documentation, but to protect against designs that have the potential to disrupt optimal care and/or generate non-individualized and non-compliant medical documents.

**HOW TO AVOID THE PERFECT STORM**

The causes of this perfect storm must be identified and eliminated. In response to these imminent dangers, practices that are currently using EHRs should obtain assistance from E/M compliance experts. They should insist that their vendors eliminate all non-compliant documentation and coding functionality related to their systems' electronic H&P, replacing such features with effective documentation tools that are usable, efficient, and compliant.

Similarly, when practices investigate the possibility of purchasing an EHR system, they should include experts in compliance and quality documentation on their evaluation team. As a condition for purchase, they should also require that these systems be usable for their physicians, efficient, contain only compliant documentation and coding tools, provide only for recording of individualized, meaningful, and reliable clinical information, and promote the quality-care process.

Figure 1 illustrates a sample blueprint for certifying that electronic H&P designs are "operable as well as interoperable." It presents standards that meet physicians' common criteria for effective medical records. These standards advocate for creative designs that not only promote quality care and meaningful documentation, but that protect against non-compliant documentation and distorted care. Physicians and practice managers would do well to require that EHR systems meet such criteria before purchase or implementation.

**THE ROLE OF EHR STAKEHOLDERS**

It is incumbent upon physicians' professional societies to seek the assistance of compliance experts and initiate policies that require corrective action for the underlying causes of these currently identified EHR system problems. This effort can include the following initiatives:

- Physician training institutions (medical schools and residency programs) should reinforce their current training for a comprehensive medical evaluation with training in E/M compliance
and with provision of efficient documentation tools that physicians can use to provide these comprehensive levels of care within the time constraints of residency and medical practice.

- EHR software vendors must provide systems whose design and functionality have the capability to guide physicians to effective care and compliant documentation, including elimination of all potentially non-compliant functionality. Further, if CCHIT does not incorporate criteria to certify these requirements, the medical societies themselves may need to establish them and provide substantive review.

- CMS must meet its own standards for compliance by requiring its fiscal intermediaries (i.e., carriers) to employ only auditing and coding tools that are compliant with the established standards in CPT and Documentation Guidelines. It must also institute a policy requiring designs to be compliant and audit-protected as a condition for EHR systems to be eligible for CMS’s payment-incentive programs.

- CCHIT has a responsibility that certification should provide meaningful protection to physicians (for systems that ensure compliance) and patients (for systems that guide and promote an optimal-care process). It should therefore incorporate high-quality criteria for functionality and compliance of the electronic H&P. These and all other criteria should be reviewed and authenticated by a consortium of medical societies and coding-compliance societies.

- HHS and the ONCHIT should modify their focus, supplementing concerns for potential fraud and abuse with an even greater focus on standards that protect physicians from non-compliant software designs and from educational approaches that impair their abilities to practice the optimal-care process that is the core of their training and their ethic.

A CLARION CALL

As the Obama administration provides incentives for the much-needed adoption of electronic health records, it must provide protections that guarantee not only the sharing of information, but also that the process of gathering this information and the quality of the information recorded are optimized. Recent audits by federal agencies confirm the warnings about E/M compliance dangers accompanying documentation shortcuts introduced by many current EHR software designs. These audits are a clarion call for stakeholders to eliminate the problems they have created, however unintended. Stakeholders must structure an environment in which physicians receive appropriate training with effective and compliant documentation tools, in which software systems provide only compliant designs and protect against improper documentation, and in which governmental agencies eliminate non-compliant practices in their own organizations and mandate compliant designs in the software systems they are advocating and promoting.

Stephen Levinson, MD, is the author of the books Practical E/M and Practical EHR. He has long focused on the interplay between compliance and quality patient care, medical ethics and integrity, and the health of the healthcare system. Deborah Grider is president of the American Academy of Professional Coders National Advisory Board. Robin Linker is executive director of operations and auditing for the Association of Healthcare Auditors and Educators, and CEO of Robin Linker & Associates Inc. Susan Thurston is executive director of education for the Association of Health Care Auditors and Educators, and CEO of Coders Connection Inc.

Send your feedback to meletters@advanstar.com
Increase in Emergency Department E/M billing levels 2002-2008

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In 2004, President Bush set as a goal that every American would have an electronic health record by 2014. In the three years since that pronouncement, the Department of Health and Human Services (DHHS) has established the Office of the National Coordinator for Health Information Technology (ONC), and the American Health Information Community (AHIC) to oversee policy. It has set priorities and has anointed two existing organizations, the Health Information Technology Standards Panel (HITSP) and the Certification Commission for Health Information Technology (CCHIT), to play significant roles in establishing and promoting the standards necessary to achieve this goal.

One theme that pervades all of the organizations involved in this broad mandate is the promotion of the adoption of electronic health records (EHRs) by physicians—a perennial issue with which the healthcare informatics community has struggled for several decades. The problem of slow EHR adoption by physicians has been described in the informatics literature as “the wave that never breaks.”1 With the emergence of the national mandate of the current administration to promote the adoption of EHRs, the introduction of legislation in Congress to fund EHR adoption and the focus of some of the 2008 presidential candidates on healthcare IT as a component of their healthcare plans, there is every indication that the wave could finally break before the end of this decade. It is therefore timely to ask if this is in the best interests of the country.

The reason that EHRs are being promoted by this administration and many others is the assumption that they can be useful tools in promoting quality and reducing costs. The premise is that the ready availability of legible patient clinical information to physicians at any place and any time would reduce errors of omission and commission resulting from the lack of such availability in the prevailing paper-based records environment. The addition of clinical decision support functions in many EHRs to alert physicians to potential errors and influence their behaviors toward evidence-based decisions further enhances the potential of EHRs to promote quality and reduce costs. All of these positive aspects of EHRs have been widely documented over several decades in the broad healthcare informatics literature and particularly in JAMIA. These will not be reviewed here.

The focus of this commentary is to question whether the current policy of promoting EHR adoption is appropriate given the current state of EHRs in the marketplace and the financial incentives currently in place to adopt them. There are some very troubling trends that have emerged in recent years that would suggest that this policy, if not modified, may backfire with regard to quality and costs. The current financial incentives to physicians to adopt EHRs are misaligned regarding the cost side of the equation.2 If, indeed, one of the benefits of EHRs is to reduce overall healthcare costs, those benefits largely accrue to the buyers of healthcare and not the providers, yet the providers currently pay for the systems. Therefore, in today’s environment, there is a financial disincentive for physicians to adopt EHRs for the purpose of healthcare cost reduction. If one couples that disincentive with the administrative and workflow disruption that the introduction of an EHR has on a medical practice at least initially, one understands why the vendors of EHRs have had to promote other features to provider organizations to convince them to purchase their products. It is these other features which have the consequence of undermining the fundamental value proposition of EHRs.

What are these other features that entice physicians to buy an EHR? They are:

1. Improved revenue from higher Evaluation and Management (E&M) codes.
2. Time saving devices for physician documentation.

From a physician’s point of view, these are both positive reasons to purchase an EHR and help overcome the financial disincentives that otherwise exist. Unfortunately, increasing the E&M codes increases overall healthcare costs rather than decreases them. It is not known whether this increase represents a correction of previous under-coding of the E&M code as some argue, or a form...
of “E&M code creep.” Regardless, the costs increase. One could argue that if the use of these EHRs reduces overall healthcare costs in other ways and/or measurably increases healthcare quality, an increase in E&M code payments could be justified. The problem is that the features introduced to enhance E&M codes and save documentation time are not the same features that improve quality or reduce overall healthcare costs. In fact, they are features that potentially degrade quality.

The biggest problem EHR vendors have faced with physician adoption is that they slow physicians down, at least initially. The fact that they might improve quality is not a sufficient inducement to a physician to use an EHR if his or her overall productivity (and therefore income) declines in the process. In documenting an encounter note, it is difficult to beat the speed of a physician dictating that note by any computer-based input mechanism except through the use of default templates and/or copying previous notes. Both of these mechanisms can greatly increase the speed of documentation by a physician. Using a single click of a mouse to enter, “The chest expansion is normal and symmetrical. There is no dullness to percussion. Both diaphragms move adequately. There are no rales, rhonchi, wheezes, egophony nor whispered pectoriloquy.” is certainly faster than dictating the same information and it certainly qualifies as adequate documentation of the chest exam for the E&M code. Faster yet is a single click for the entire physical exam or even more complete notes which can be done in some systems. With regard to the copy/paste feature, if one is following a patient that is relatively stable and has had little or no change from the previous visit, it is certainly faster to copy and perhaps make minor edits to a previous note than to re-create one. These two mechanisms (defaults and copy/paste) have become widespread in EHR products and raise the question whether adoption of EHRs, in their present form, should be promoted.

There have been no studies yet published that scientifically measure the quality of documentation of EHRs with these time-saving features. However, there is mistrust of EHRs produced in this manner. Computer print-outs of encounter notes with complete reviews of systems and physical exams with dozens of normal negatives neatly documented are largely discounted by the physicians who receive them. An article published recently in the Sacramento Bee newspaper illustrates the problem. It describes a conversation between two physicians in which the first physician, in commenting on the progress note produced by the second physician says, “Wow, that’s a very thorough note. You completed that entire exam and asked all those questions in 15 minutes?” The second physician responded, “Not really. It was entered by an electronic template.” The article concludes that such practices “may hinder care and could lead to major problems.” A recent article in JAMA on the problem of the use of copy/paste has a similar theme. These are admittedly anecdotal examples and not proof that the EHRs with these features reduce quality. However, if one understands how physicians work and how these EHRs function, it is easy to understand how inaccurate documentation can become a part of the most well-intentioned physician’s practices. Physicians are generally rushed when seeing patients. That is why they seek time-saving devices in the first place. Default notes and copying previous notes are helpful in saving time. But editing a default note or a copied note that is not quite applicable to the current visit is time-consuming in any system. Even proof-reading them is a distraction when a physician is in a hurry. It is understandable that in the course of click-producing many notes a day, there may be insufficient time to read and edit out one or two aspects of the default or copied history or physical that are not accurate or might not have been asked or performed at the current encounter. Either this editing simply is not done, or sometimes the physician will dictate or type a supplemental free-text portion of the note with the correct information creating an inconsistency in the final note. Unfortunately because physicians are paid on the basis of what they document, the defaults built into most systems tend to be the maximum documentation of what they normally do rather than the minimum. These notes do increase the E&M code value and therefore the revenue of the physician and they do save physician documentation time. However if, as it seems likely, they are not always accurate reflections of the encounter, they have delivered a serious blow to the quality of documentation and, one can argue, quality of care as well. Even though there are other quality benefits of these systems, this cannot justify the acceptance of degraded and potentially misleading documentation. Further, if other physicians discount all or some of these notes as untrustworthy, what purpose do they serve other than as documents to support claims? One should not be surprised when we see articles, such as the recent publication in the Archives of Internal Medicine, indicating a lack of evidence that EHRs improve quality.

There is one other potentially ominous aspect to EHRs that also must be considered. Under a contract from ONC, a group of experts was commissioned in 2005 to examine the issue of healthcare fraud as it relates to information technology. The report from this effort highlighted the huge cost problem which fraud currently represents ($51B to $170B in 2003). More significantly, the report warned that unless specific measures are taken, the opportunity for fraud greatly increases as the healthcare system becomes increasingly electronic. Among the 10 “guiding principles” recommended in this initial report was the following:

“EHR standards must define requirements to promote fraud management and limit opportunities for fraud and abuse.”

In 2006, as a part of a second contract issued by ONC, another group of experts was commissioned to recommend an initial set of such requirements. The expert panel acknowledged that only a very small minority of physicians commit fraud and attempted to define recommendations that not only would help in fraud management, but also help to promote better documentation practices for all physicians using EHRs. A draft of these requirements was made available for public comment and the final set of recommended requirements is currently under review by both HITSP and CCHIT. Although the outcome of this process will not be known for some time, the prospects are uncertain for widespread incorporation of the recommended fraud management functions into commercial EHRs. These recommended functions largely relate to increased audit capability of the “who, what, when, how, and why” of documentation and access to clinical information.
Judging from the initial informal feedback from some members of HITSP and CCHIT and public commentary from physician organizations regarding the report, attempting to build in fraud management functions would be perceived as threatening to physicians and/or could add undesired cost increases for EHR systems. If either is true, EHR adoption would be inhibited by these functions—just the opposite of what these organizations are mandated to do and certainly not in the vendors’ interests.

The current policy of promoting adoption of EHRs requires some re-thinking. Adoption, per se, is not the goal. We must focus, in addition, on correcting the problems in EHRs and more importantly, on the financial environment which underlies those problems. DHHS, ONC, AHIC and the entire informatics community need to re-focus their priorities on promoting EHRs that enhance quality, cost reduction and fraud management even at the risk of delaying adoption.

References
In reviewing the criteria required for CCHIT credentialing, the American Academy of Professional Coders uncovered multiple areas for concern. Many of the CCHIT requirements conflict with federal mandates for correct coding or with what AAPC promotes as appropriate coding principals. What follows is a catalog of some of CCHIT’s principal flaws, quoting (in italics) CCHIT source documents followed by a discussion of the problem each specific criterion creates, and proposed solutions to these problems. The flaws are:

**Flaw #1: Ignores Coding Rules.**

CCHIT requires codes be provided, but it does not require rules driven coding. The physician can select any code he/she chooses, without consideration of guidelines or compliance issues.

**Flaw #2: Promulgates Bad Data.**

CCHIT encourages the use of pick-lists for code selection, which won’t provide effective data.

**Flaw #3: Generates Fraudulent CPT Coding.**

CCHIT auto-selects elements of evaluation and management coding without consideration of medical decision making.

**Flaw #4: Puts Physicians in Harm’s Way.**

CCHIT inadvertently provides a framework for cloning data that may lead to institutionalized upcoding, putting physicians in harm’s way.

**Flaw #5: Provides a Lesson in Misdirection.**

In today’s hyper-regulatory healthcare environment, compliance is a very important word. And CCHIT is misusing it.

**Flaw #1: Ignores Coding Rules**
CCHIT requires codes be provided, but it does not require rules driven coding. The physician can select any code he/she chooses, without consideration of guidelines or compliance issues.

**Manage problem list:** Create and maintain patient specific problem lists.

(Original line 234 in Phase 1 CCHIT Ambulatory Functionality source document)

7. The system shall provide the ability to associate orders, medications and notes with one or more problems; association to be structured, codified data.

8. The system shall provide the ability to maintain a coded list of problems.

For example: ICD-9-CM, ICD-10-CM, SNOMED-CT, DSM-IV. The Functionality WG will not specify which code set(s) are to be employed.

If physicians are selecting codes in their EMRs, they are doing so using pick lists that are a subset of the full code sets (which totals more than 28,000 codes). EMR pick lists are not in compliance with coding standards as outlined by the OIG (OIG Compliance Program for Individual and Small Group Physician Practices, published in the Federal Register, Volume 65, No. 194, Oct. 5, 2000, page 59439).

According to OIG’s recommendations, all coding should follow “the official coding guidelines are promulgated by HCFA, the National Center for Health Statistics, the American Hospital Association, the American Medical Association, and the American Health Information Management Association. See International Classification of Diseases, 9th Edition, Clinical Modification (ICD-9-CM) (and its successors); 198 Health Care Financing Administration Common Procedure Coding System (HCPCS) (and its successors); and Physicians’ CPT. In addition, there are specialized coding systems for specific segments of the health care industry.”

The complex guidelines within CPT®, ICD-9-CM, and HCPCS are not available in pick-lists or cheat sheets, and this practice therefore leads to coding errors. The Obama Administration is calling for wholesale adoption of EMRs within six years.

At the same time, CMS is targeting EMRs in its compliance audits. Medicare Compliance Alert, on May 29, 2006,( Medicare Compliance Alert, Vol. 18, No.11, Page
warned that “On a page obtained by Medicare Compliance Alert from an internal National Medicare Fraud Alert, CMS notifies state and federal government law enforcement agencies about the ‘use of medical documentation software programs in a manner that results in the upcoding of office evaluation and management services.’” The 2009 OIG Workplan: (http://www.oig.hhs.gov/publications/docs/workplan/2009/WorkPlanFY2009.pdf) also targets E/M reporting rules that contain nuances that are difficult for EMRs to query and for physicians to apply consistently.

**AAPC recommends** that codes be omitted from EMR credentialing requirements. Automated coding is an EMR vendor sales point that has failed to deliver quality in the marketplace. Instead, focus EMR credentials on pertinent issues of portability, interoperability, security, privacy, and clinical quality. As part of the interoperability requirement, require EMRs to be able to dovetail with software systems that specialize in coding. For the physician who has time to code, this could be a software system with complex and complete code lookup capabilities. For the physician who doesn’t code, it allows the EMR to link to the next generation of coding, which may be computer-assisted coding software or some other software. These systems would be purchased separately as adjunct to EMRs because coding software requires expertise and evolving knowledge bases too complex to include in the base EMR requirements. Selected codes should always be audited by professional coders before the claims are filed, as clinicians don’t have the time or resources to keep abreast of all the coding rules.

**Flaw #2: PROMULGATES BAD DATA**

**CCHIT encourages the use of pick-lists for code selection, which won’t provide effective data.**

*Manage clinical documents and notes:* Create, correct, authenticate, and close, as needed, transcribed or directly entered clinical documentation.

(Original line 54 in Phase 1 CCHIT Ambulatory Functionality source document)

18. The system shall provide the ability to associate standard codes with discrete data elements in a note.
Examples include but are not limited to SNOMED-CT, ICD-9 CM, ICD-10 CM, DSM-IV, CPT-4, MEDCIN, and LOINC. This would allow symptoms to be associated with SNOMED terms, labs with LOINC codes, etc. The code associated with a note would remain static even if the code is updated in the future.

There are more than 28,000 valid medical codes within ICD-9-CM, CPT, and HCPCS. To include all appropriate codes in pull-down menus or pick lists is sometimes easy, but getting to those codes may be complex. For example, there are only three joint injection codes in CPT: one for the major, one for intermediate, and one for minor joints. This makes for an easy pick-list for physicians. However, the diagnostic codes that map to these three CPT codes number in the hundreds, in part because the symptoms/disorders that would require an injection are many, and in part because each joint is enumerated with a code (i.e., 719.01 for effusion of shoulder joint; 719.05 for effusion of hit point).

It’s difficult to get all the appropriate codes winnowed into a manageable list. In the past 20 years, what has emerged as a workaround for lengthy pick-lists is a trend toward nonspecific codes (i.e., 719.00 for effusion of joint, site unspecified or 719.08 for effusion of joint, other specified sites) instead of the more specific codes.

CMS has long recommended against using “cheat sheets” or pick lists for coding (See Lessons for All Coders, TriSpan Health Services, [http://www.trispan.com/factsheets/ICD9CodingCompliance.pdf](http://www.trispan.com/factsheets/ICD9CodingCompliance.pdf)).

This is partly because short lists don’t provide the coding guidance found within code books, but primarily because a truncated list does not promote specificity in coding. The ICD-9-CM Coding Guidelines tell us, “Unspecified codes are for use when the information in the medical record is insufficient to assign a more specific code.” Yet EMRs regularly use nonspecific codes on pick-lists for physicians who know, in most cases, exactly what is wrong with the patient.

CMS wants specificity in coding because medical codes are used to shape payments and policies, and because they contribute to the study of outcomes that advance evidence based medicine. CMS cites specificity as a major reason to implement ICD-10-CM and ICD-10-PCS, new coding systems that greatly expand the detail provided in coding. The Final Rule for ICD-10, published in the Federal Register (Vol. 74, No. 11, Friday, Jan. 16, 2009, [http://edocket.access.gpo.gov/2009/pdf/E9-743.pdf](http://edocket.access.gpo.gov/2009/pdf/E9-743.pdf)) states, “We anticipate that the use of ICD-10-CM, with its greater detail and granularity, will greatly enhance our capability to measure quality outcomes....The greater detail and granularity of ICD-10-CM and ICD-10-PCS will also provide more precision for claims-based, value-based purchasing initiatives.” This can only occur if the data provided in the codified medical record is as specific as possible. If pick
lists continue to promote “dump codes,” the United States will not see the financial or clinical benefits outlined in the Final Rule.

**AAPC recommends again** that codes be omitted from EMR credentialing requirements. Instead, focus EMR credentials on pertinent issues of portability, interoperability, security, privacy, and clinical quality. As part of the interoperability requirement, require EMRs to be able to dovetail with software systems that specialize in coding.

**Flaw #3: GENERATES FRAUDULENT CPT CODING**

**CCHIT auto-selects elements of evaluation and management coding without consideration of medical decision making.**

**Rules-driven financial and administrative coding assistance:** Provide financial and administrative coding assistance based on the structured data available in the encounter documentation.

*(Original line 234 in Phase 1 CCHIT Ambulatory Functionality source document)*

1. The system shall have the ability to provide a list of financial and administrative codes.

   For example, ICD-9 CM, ICD-10 CM, and CPT-4 codes.

2. The system shall provide the ability to select an appropriate CPT Evaluation and Management code based on data found in a clinical encounter. May be accomplished via a link to another application.

3. The system shall have the ability to provide assistance in selecting appropriate billing codes based on codified clinical information in the encounter.

   Criterion satisfaction will require that the system can automatically count elements in the history and examination documentation to accomplish this calculation. MDM complexity will still require specification by the provider/coder.

Selection of evaluation and management codes requires a complex equation of many elements. Missing from the CCHIT “auto-coding” system is a key element: medical decision making. While the criteria states that “MDM complexity will still require specification by the provider/coder,” because it is
the sole element lacking, its absence will be overlooked. Errors will be made. Furthermore, EMR pick lists are not in compliance with coding standards as outlined by the OIG. If physicians are selecting E/M levels in their EMRs, they are doing so using pick lists that are a subset of the full code sets (which totals more than 100 codes). To require there be codes in the EMR without requiring there be access to a guidelines and instructions sets the stage for noncompliance.

It’s worth noting here that professional coders are constantly honing their skills and working to keep up with the rule changes in coding. Certified coders are required to obtain nearly 20 hours of education every year. Physicians have their own continuing education requirements, but these are spent with clinical issues, as they should be. A half-baked code selection process like the one that CCHIT certifies does a disservice to physicians, who depend on the certification to keep them compliant and accurate.

**AAPC recommends** that the certifying body for EMRs limit its criteria for coding to those areas regarding clinical documentation. Robust clinical documentation will ensure proper coding, whether performed by a physician or computer-assisted coding, and reviewed by a certified professional coder.

Flaw #4: PUTS PHYSICIANS IN HARM’S WAY.

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**CCHIT inadvertently provides a framework for cloning data that may lead to institutionalized upcoding, putting physicians in harm’s way.**

**Manage clinical documents and notes:** Create, correct, authenticate, and close, as needed, transcribed or directly entered clinical documentation.

*(Original line 54 in Phase 1 CCHIT Ambulatory Functionality source document)*

21. The system shall provide templates for displaying medical summary data in a structured format.

*Examples might include the continuity of care record or the DCA. This requirement does not specify a particular format although many vendors will choose to use the harmonized CCR/CDA/CRS once available.*

One of the key components of CCHIT’s criteria is management of patient history, which in addition to being an important component of the clinical picture, is also a factor in determining the level of E/M. Medicare has identified E/M leveling by EMRs as a compliance risk, because information not gathered
during the current encounter can be weighted to raise payment for the physician. Pinnacle’s position (PBSI Medicare Services for the state of Arkansas, SEM 090808 published 9/23/2008 http://www.arkmedicare.com/provider/viewarticle.aspx?articleid=6438) is:

With the advent of increasingly popular Electronic Medical Record (EMR) templates has come an increased risk of noncompliance. Although many positive aspects related to EMRs have been identified, they may also lead to “cloning” of medical records if not properly used. Each E/M service should stand alone. According to the 1997 Documentation Guidelines for E/M Services, “Medical record documentation is required to record pertinent facts, findings, and observations about an individual’s health history...” Medical record cloning will not satisfy that E/M requirement.

In the July 2008 article, “Electronic Medical Records May Lead To Decreased Payment” (Pinnacle Medicare Providers News, page 41, http://www.arkmedicare.com/provider/provnewslet/pdfformat/mcb200807.pdf), it stated:

Medicare Contractors are noting increasing frequency of cloned records. Each E/M service should stand alone. When no documentation differences are noted for several services for one beneficiary or for services for multiple beneficiaries, there may be a question of potential fraud. According to Change Request (CR) 5644, Transmittal 252, “The PSC [Program Safeguard Contractor] shall determine if patterns and/or trends exist in the medical record which may indicate potential fraud, waste or abuse. Examples include, but are not limited to:

- The medical records tend to have obvious or nearly identical documentation
- In reviews that cover a sequence of codes (Evaluation & Management codes, therapies, radiology, etc.) there may be evidence of a trend to use the high ends codes more frequently than would be expected...

Safeguards specific to cloning are not in place in CCHIT credential criteria because, AAPC contends, physician coding experts were not engaged in the criteria development process. As a result, physicians are being held liable for overcharges they didn’t intend, couldn’t predict, and don’t understand.

**AAPP again recommends** E/M selection be performed by software or by the clinician, and then reviewed by a certified coding professional.

**Flaw #5: PROVIDES A LESSON IN MISDIRECTION.**
In today’s hyper-regulatory healthcare environment, compliance is a very important word. And CCHIT is misusing it.

**Clinical decision support system guidelines updates:** Receive and validate formatted inbound communications to facilitate updating of clinical decision support system guidelines and associated reference material

*(Original line 244 in Phase 1 CCHIT Ambulatory Functionality source document)*

1. The system shall provide the ability to update the clinical content or rules utilized to generate clinical decision support reminders and alerts. Growth charts, CPT-4 codes, drug interactions would be an example. Any method of updating would be acceptable. Content could be third party or customer created.

2. The system shall provide the ability to update clinical decision support guidelines and associated reference material. Any method of updating would be acceptable. Content could be third party or customer created.

The biggest disservice that CCHIT has done for its provider population is to say a certified EMR meets the criteria for “compliance.” For providers today, the word “compliance” is forever linked to coding compliance. But there is no coding compliance in CCHIT certification. As it says above “Any method ... is acceptable.” It even suggests the complex updates for coding systems could be “customer created.” The whole issue of coding with CCHIT is laissez-faire: There are no rules provided and no guarantees given.

The OIG Compliance Program for Individual and Small Group Physician Practices lists the following components for compliance:

This compliance program guidance for individual and small group physician practices contains seven components that provide a solid basis upon which a physician practice can create a voluntary compliance program:

- Conducting internal monitoring and auditing;
- Implementing compliance and practice standards;
- Designating a compliance officer or contact;
• Conducting appropriate training and education;

• Responding appropriately to detected offenses and developing corrective action;

• Developing open lines of communication; and

• Enforcing disciplinary standards through well-publicized guidelines.

All seven points focus on coding and reimbursement. With the advent of RAC and private payer audits, providers are feeling the pinch of regulatory scrutiny like no other business group. To suggest a word like “compliance” is appropriate to a piece of software that only dabbles in codes gives providers a false sense of confidence.

**AAPC recommends** that whatever course is taken regarding criteria, the term “certification” is replaced with another less ambiguous term so providers are not mislead as to what a system can provide them. Possible replacement terms include sanctioned, recognized, tested, or proven.
The National Health Care Anti-Fraud Association estimates that the annual cost of healthcare fraud is somewhere between 3% and 10% of total healthcare costs. That estimate is not only astounding because of its magnitude, but also because of its range, indicating uncertainty. The sum of $100B per year, one way or another, matters. For example, that difference would fund all of the imagined Nationwide Health Information Network (NHIN) in any of its possible forms and a whole lot more.

The Office of the National Coordinator for Health Information Technology (ONC) has completed two contracts related to healthcare fraud. The first, performed by the Foundation on Research and Education of the American Health Information Management Association, issued a report in 2005 in which an expert panel recommended a set of “Guiding Principles” for health information technology relating to healthcare fraud management. (“Fraud management” is defined as the prevention, detection and prosecution of fraud.) The second contract, performed by RTI International, issued a report in 2007 in which a second expert panel recommended 14 requirements for electronic health records related to healthcare fraud management. I served as the co-chairman of the first expert panel and the chairman of the second expert panel. It is my experience with these two panels and the subsequent industry reaction that prompts the title of this paper.

In our kickoff meeting under the first contract, Dr. David Brailer, in giving the charge to our panel, asked us to answer the question, “Should the emerging NHIN play a role with regard to reducing healthcare fraud and, if so, what role?” The ensuing contract process involved an extensive review of the literature, on-site interviews with multiple healthcare stakeholders including providers, consumers, payers, healthcare economists, law enforcement, and technology organizations. The expert panel, which included representatives from all of these stakeholders, reviewed the results of this fact gathering process, heard presentations from various outside experts, and deliberated regarding Dr. Brailer’s question.

The result was a set of Guiding Principles, the first of which was, “The Nationwide Health Information Network (NHIN) policies, procedures, and standards must proactively prevent, detect, and reduce healthcare fraud rather than be neutral to it.” The reason for this conclusion was the universal opinion of the experts that the potential for fraud increases in an electronic environment and without proactive steps in fraud management, our enormous problem will get worse. Further, experience has shown that it is far more effective to prevent fraudulent payments than to “pay and chase,” which is the predominant model in use today. Since we are still early in the use of EHRs and interoperable networks, now is the time to anticipate this problem.

Another Guiding Principle of the first report was, “EHR standards must define requirements to promote fraud management and minimize opportunities for fraud and abuse, consistent with the use of EHRs for patient care.” This was the basis for the second contract with RTI International which convened another expert panel to make recommendations for such requirements for EHRs. These recommendations were intended to specifically inform the processes of both the Health Information Technology Standards Panel (HITSP) and the Certification Commission for Health Information Technology (CCHIT). This second expert panel consisted of some of the panel members from the first contract plus additional stakeholders from the provider community with EHR and EHR vendor experience. The panel process involved the development of use cases for the commitment of fraud by those using EHRs and brainstorming among the panel members for possible fraud management solutions that could be built into EHRs. The panel divided into two groups: those developing recommendations that would be useful in preventing the commission of fraud and/or detecting fraud prior to payment of a claim, and a second group developing recommendations to assist in fraud detection after payment and assist in prosecution. Draft recommendations went through multiple iterations within the panel and a reduced set was made available for public comment. The public comments were subsequently reviewed in detail by the panel and recommendations were modified or eliminated as a result for the final report.

The original set of Guiding Principles received uniform praise and support from all segments of the healthcare industry. The recommendations for EHRs from the second report did not. Most of the public comments during the second contract regarding the EHR recommendations were supportive, but a substantial number raised concerns. Likewise, following the publication of the final report, there was support for most of the recommendations but a significant
amount of pushback on many of them. The difference in the industry reactions to the two reports is not surprising. The Guiding Principles of the first report were high level, general, and somewhat like “motherhood” in nature. The recommendations of the second report were specific, tough, and would require significant actions on the part of the healthcare IT industry that would compete with other priorities. Pushback and debate is both healthy and expected.

The concerns raised about the EHR recommendations were that they could violate consumer and physician privacy, allow payers unwarranted access to electronic records, be threatening to physicians regarding fraud investigation, add cost to EHRs, and impede performance of EHRs. To the extent that any of these is true, they are legitimate issues and would have a negative impact on adoption of EHRs. The expert panel took all of these potential issues into consideration and crafted the final recommendations in a manner which would either eliminate them or mitigate them to an acceptable level commensurate with the problem. Nonetheless, there is room for continued debate and reworking of the solution.

What is not an acceptable solution is to totally dismiss the notion of building fraud management into EHRs as some are advocating. Admittedly there is a cost to doing this and there is some competition with other priorities. It became clear during our interaction with both CCHIT and HITSP that fraud management was not on either organization’s radar screen. Although the leadership of both organizations expressed support for dealing with the fraud problem, it was also clear that neither organization had received any mandate from the American Health Information Community (or anyone else) to put it as a priority. Further, the notion of requiring EHR vendors to implement functions that would, in part, help payers or law enforcement agencies to prosecute their customers would be not only be politically incorrect for organizations that depend on vendor and provider support but is perceived as conflicting with their primary goal of promoting EHR adoption. EHR adoption is an important goal, but we cannot have an attitude of EHR adoption regardless of any potential negative consequencess.10 Apparently, somewhere in the background of this process, ONC or someone else in DHHS also became nervous about being too visible about pushing fraud management as a high priority. After our panel completed its work and contributed to writing multiple drafts of our final report, the report did get published under the title, “Recommended Requirements for Enhancing Data Quality in Electronic Health Record Systems.”

That report title is not quite as misleading as it appears. Although our entire process was focused on fraud management, data quality of health records for patient care is inseparable from the issue of fraud. Records that are complete, accurate and medically appropriate are not fraudulent. However, the fraud management piece requires additional metadata about the “who, what, when, and how” of record completion in order to help sort out the minority bad guys from the majority good guys. It is not a simple process and the better the documentation, the easier it is to perform a fraud management function. And, by the way, these same metadata also protect the good guys from inappropriate suspicion of fraud.

We have a problem. “We” means everyone: consumers, payers, providers, and healthcare IT professionals. The sum of $200B per year (or whatever is the true amount) is not “chump change.” The fact that we don’t even know the true amount is a problem. The fact that we don’t really know how many of our providers commit fraud is a problem. The best estimate of that number that I have been able to glean from authorities in CMS who should know is that it is “less than a majority.” We need to be more precise about that. Whatever the current amount of fraud is, as stated earlier, the widespread opinion is that without proactive fraud management built into our IT infrastructure now, the problem will become significantly worse. After interacting with people from CMS, the Office of the Inspector General and officials in the Department of Justice, I have the distinct impression that their view is that the healthcare IT community does not take this problem seriously.

I interpret the reaction of the healthcare IT community differently. We do take this problem seriously and no one wants to see EHRs become facilitators of fraud. The concerns expressed, however, especially the potential threat to EHR adoption, are considered equally serious. I believe we can turn this threat into an opportunity. The link between fraud management and quality of records for patient care is real. The improved security tools and increased metadata that are required for fraud management are threats to the bad guys and protection for the good guys. The opportunity is on the financial side. Recent comments from the Director of the Congressional Budget Office suggest that EHRs may not be cost-effective and deserving of Federal investment.11 If we can demonstrate that EHRs will make even a small dent in the huge cost of healthcare fraud, this can become the major financial justification for them.

In my view, the next steps need to bring all of the parties together to work on this problem. Specifically, we need to better quantify and characterize the current fraud problem and better quantify and characterize the expected increase with EHRs. This type of quantitative data was lacking in the two ONC reports and is required not only to help convince a skeptical healthcare IT community, but to better prioritize and cost-justify the EHR functions required to mitigate the problem. In the meantime, many of the recommendations for EHRs are not controversial and we should implement now these “low hanging fruit” recommendations for fraud management. These include requirements for increased audit information and protection of audit processes, use of the National Provider Identifier in audit logs of provider input, enforcement of strong user authentication, record modification rules and tracking, improved output document tracking, increased security for electronic transmissions, and a clear definition of the minimal requirements for the legal EHR for business purposes.

In summary, the ONC contracts have succeeded in putting fraud management on the table. It is our responsibility as healthcare IT professionals to make sure it doesn’t get “tabled”.

References


Variations and Trends in the Coding of Evaluation and Management (E&M) Services by Hospital Emergency Departments

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Variations and Trends in the Coding of Evaluation and Management (E&M) Services by Hospital Emergency Departments

Summary

Following implementation of the Medicare Outpatient Prospective Payment System (OPPS), unexpected variances have been observed in the assignment of evaluation and maintenance (E&M) codes on emergency department claims. Hospital OPPS claims were used to define normal Medicare payment levels and distributions of patients among various levels of E&M codes for calendar years 2002-2004. Data for some hospitals indicate that there may be systematic under-coding or over-coding of emergency department encounters. Under-coding can result in lower levels of reimbursement, while over-coding can be a compliance problem requiring immediate intervention and correction. The findings of this study should be useful in helping a hospital to determine whether its E&M coding is within expected ranges.

Background

Medicare implemented the OPPS for hospital outpatient services in 2000. Under this system a hospital is paid fixed rates for various Ambulatory Payment Classifications (APCs). The procedures detailed on a Medicare patient’s bill are grouped into these APCs in order to determine payment. Complete and accurate coding of procedures is therefore essential in ensuring that a hospital receives accurate payment.

This study focuses on the assignment of E&M codes in a hospital emergency department (ED). These codes are frequently used and are sometimes problematic. Coding guidelines for E&M codes have been somewhat ambiguous for hospital use under the OPPS, and incorrect coding can result. This study assesses the potential prevalence of such errors.

Sources and Limitations of Data

This study is based on Medicare OPPS claims for hospital ED visits during calendar years 2002 through 2004. Data were obtained from the Centers for Medicare and Medicaid Services (CMS) and contain fee-for-service claims data for Medicare hospital outpatient bills. All data obtained from CMS and used in this analysis are consistent with CMS Data Release Policies.

When reviewing this analysis it is important to note that the entire population of Medicare ED patients is not represented.

- Medicare patients who are admitted to a hospital through its Emergency Department are not included in outpatient claims data. (Medicare does not allow hospitals to bill separately for outpatient services provided prior to an admission.) Therefore, admitted patients are not included in this analysis.
• Patients covered by a Medicare managed care plan also are excluded, since the CMS outpatient data include only fee-for-service claims.

• Critical Access hospitals are not included in OPPS claims data.

It should also be noted that some hospitals are consolidated for reporting. A single Medicare provider number may actually represent multiple physical hospitals. This can distort analytics based on hospital size.

Evaluation and Management Codes

Evaluation and Management services are represented by six CPT codes that group into four APC categories representing a range of resource consumption. Definitions and national payment rates for these APCs are updated annually by CMS.

Table 1 – APC Definitions and Payment Rates

<table>
<thead>
<tr>
<th>APC</th>
<th>Definition</th>
<th>CPT</th>
<th>2002</th>
<th>2003</th>
<th>2004</th>
<th>2005</th>
<th>2006</th>
</tr>
</thead>
<tbody>
<tr>
<td>610</td>
<td>Low level emergency visits</td>
<td>99281</td>
<td>$62.61</td>
<td>$73.78</td>
<td>$74.70</td>
<td>$77.18</td>
<td>$73.79</td>
</tr>
<tr>
<td></td>
<td></td>
<td>99282</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>611</td>
<td>Mid level emergency visits</td>
<td>99283</td>
<td>$109.95</td>
<td>$131.89</td>
<td>$130.77</td>
<td>$136.34</td>
<td>$129.18</td>
</tr>
<tr>
<td>612</td>
<td>High level emergency visits</td>
<td>99284</td>
<td>$177.65</td>
<td>$226.39</td>
<td>$226.30</td>
<td>$234.42</td>
<td>$224.78</td>
</tr>
<tr>
<td></td>
<td></td>
<td>99285</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>620</td>
<td>Critical care</td>
<td>99291</td>
<td>$427.59</td>
<td>$519.48</td>
<td>$491.01</td>
<td>$516.54</td>
<td>$477.73</td>
</tr>
</tbody>
</table>

Since E&M codes were originally designed for physician or professional services reporting, the assignment of these codes was originally based on factors such as the detail of patient history, extent of patient examination, complexity of medical decision making, and whether the patient was critically ill or injured.

According to guidance published in the Federal Register, “Coding guidelines for emergency and clinic visits should be based on emergency department or clinic facility resource use, not physician resource use.” In other words, the CPT definitions developed for physician reporting are not appropriate for hospital reporting. Even though the regulations make it clear that physician guidelines should not be used for reporting hospital resource use, they do not provide specific criteria for the assignment of these codes in the hospital setting. Instead of specific criteria there are guidelines presented in the Federal Register that hospitals can follow to develop their own criteria:

• Coding guidelines for emergency and clinic visits should be based on emergency department or clinic facility resource use, not physician resource use.

1 CPT codes copyright 2005 American Medical Association. All Rights Reserved. CPT is a trademark of the AMA. No fee schedules, basic units, relative values or related listings are included in CPT. The AMA assumes no liability for the data contained herein. Applicable FARS/DFARS Restrictions Apply to Government Use.

2 42 CFR Part 405, August 9, 2002, page 52131
• Coding guidelines should be clear, facilitate accurate payment, be usable for compliance purposes and audits, and meet HIPAA requirements.

• Coding guidelines should only require documentation that is clinically necessary for patient care. Preferably, coding guidelines should be based on current hospital documentation requirements. (This guideline discourages separate scoring sheets.)

• Coding guidelines should not facilitate up-coding or gaming.

• The distribution of codes should result in a normal curve. Documentation guidelines should support this result.

The “normal” distribution curve was described as, “The distribution of all emergency services is in a bell-shaped curve with a slight left shift because there are more claims for CPT codes 99281 and 99282 than for codes 99284 and 99285.” The graph in Table 2 shows the trend in this curve from 2002 to 2004. Note in 2004, the slight shift of the curve to the right. This indicates that more patients are being classified with higher levels of E&M (99284) and fewer patients in the lower levels. Though some of this shift may reflect acuity, some may also be attributable to changes in documentation and coding practices by the hospital.

Table 2 – Shift in the distribution of CPT codes from 2002 to 2004

The acuity of patients (and their APC mix) may differ across hospital emergency departments according to factors such as:

• the characteristics of the population served
• the range and complexity of services offered
• hospital size and specialties
• referral relationships among hospitals in an area
• regional influences on healthcare
Though there are clearly defined shifts in the aggregate, data show remarkable variability among individual hospitals. In order to better understand this variability hospitals were categorized according to their annual emergency department claims volume in 2004 (i.e. the total number of claims with APCs 610, 611, 612, or 620). Hospitals with fewer than 500 claims during calendar year 2004 were excluded. It was felt that hospitals with fewer than 500 claims had only minor ED operations (i.e. fewer than two Medicare patients on average per day) and did not have sufficient volumes for analysis.

Table 3 – Distribution of Hospitals According to ED Volumes in 2004

<table>
<thead>
<tr>
<th>Category Based on Annual ED Claims</th>
<th>Number of Hospitals</th>
<th>Total Claims</th>
<th>Average Claims/Hospital</th>
</tr>
</thead>
<tbody>
<tr>
<td>500 - 1,000</td>
<td>225</td>
<td>174,768</td>
<td>777</td>
</tr>
<tr>
<td>1,001 - 4,000</td>
<td>2,108</td>
<td>4,995,630</td>
<td>2,370</td>
</tr>
<tr>
<td>4,001 - 7,000</td>
<td>769</td>
<td>3,968,442</td>
<td>5,161</td>
</tr>
<tr>
<td>7,001 - 10,000</td>
<td>162</td>
<td>1,320,740</td>
<td>8,153</td>
</tr>
<tr>
<td>&gt;10,000</td>
<td>54</td>
<td>679,380</td>
<td>12,581</td>
</tr>
<tr>
<td>Totals</td>
<td>3,318</td>
<td>11,138,960</td>
<td>3,357</td>
</tr>
</tbody>
</table>

For each volume category, the distribution of claims among the four APCs was examined:

Table 4 – Distribution of APCs According to Hospital Volumes in 2004

<table>
<thead>
<tr>
<th>Annual ED Claims</th>
<th>APC 610 (low)</th>
<th>APC 611 (mid)</th>
<th>APC 612 (high)</th>
<th>APC 620 (critical)</th>
</tr>
</thead>
<tbody>
<tr>
<td>500-1,000</td>
<td>38.3%</td>
<td>33.5%</td>
<td>26.5%</td>
<td>1.7%</td>
</tr>
<tr>
<td>1,001 - 4,000</td>
<td>32.1%</td>
<td>35.5%</td>
<td>31.1%</td>
<td>1.3%</td>
</tr>
<tr>
<td>4,001 - 7,000</td>
<td>28.8%</td>
<td>34.4%</td>
<td>35.7%</td>
<td>1.1%</td>
</tr>
<tr>
<td>7,001 - 10,000</td>
<td>24.0%</td>
<td>33.7%</td>
<td>41.4%</td>
<td>0.9%</td>
</tr>
<tr>
<td>&gt;10,000</td>
<td>26.1%</td>
<td>36.7%</td>
<td>36.6%</td>
<td>0.6%</td>
</tr>
<tr>
<td>Averages</td>
<td>29.7%</td>
<td>35.0%</td>
<td>34.3%</td>
<td>1.1%</td>
</tr>
</tbody>
</table>

Smaller emergency departments provide a higher proportion of lower intensity services (i.e. those hospitals with lower numbers of annual ED claims had a higher proportion of patients with APC 610 - the lowest level of emergency visits). Conversely, larger emergency departments provided higher proportions of higher intensity services (i.e. APC 611 and APC 612).

It would seem logical to expect larger emergency departments to also provide higher proportions of critical services (i.e. APC 620). However, the data seem to indicate just the opposite. The most likely reason for this is that critical patients are more often admitted as inpatients in larger hospitals, and therefore do not appear in the outpatient data. On the other hand, critical patients are often transferred from smaller hospitals to larger ones (instead of being admitted to the smaller hospital). Consequently, such transferred patients do appear in the outpatient data for the smaller hospitals.

Using Average Reimbursement as an Index of Patient Mix

Medicare pays a fixed rate for each APC according to national payment rates that are updated periodically. Because these rates are based on national median costs, they are a
good proxy for relative intensity of service among APCs. For payment purposes this rate is normally adjusted to account for wage differences among hospitals in different geographic areas. For this study, however, we used unadjusted national rates to calculate and compare average payment among hospitals. This average payment based on national rates serves as an acuity index that reflects the distribution of patients among the various APCs. (National payment rates for each APC appear in Table 1 of this study.)

Table 5 – Average E&M Payment According to Hospital Volumes in 2004 (national payment rates)

<table>
<thead>
<tr>
<th>Annual ED Claims</th>
<th>Average Payment (national rates)</th>
<th>Avg. Pmt. Range (lowest - highest)</th>
</tr>
</thead>
<tbody>
<tr>
<td>500-1,000</td>
<td>$141</td>
<td>$75 - $246</td>
</tr>
<tr>
<td>1,001 - 4,000</td>
<td>$147</td>
<td>$77 - $258</td>
</tr>
<tr>
<td>4,001 - 7,000</td>
<td>$153</td>
<td>$87 - $282</td>
</tr>
<tr>
<td>7,001 - 10,000</td>
<td>$160</td>
<td>$97 - $219</td>
</tr>
<tr>
<td>&gt;10,000</td>
<td>$153</td>
<td>$104 - $199</td>
</tr>
<tr>
<td>Total</td>
<td>$151</td>
<td>$75 - $282</td>
</tr>
</tbody>
</table>

Higher volume emergency departments commonly treat higher-acuity patients and would be expected to have the highest average payment. In this analysis, however, the largest ED operations reporting >10,000 outpatient visits did not have the highest average payments. Since such hospitals typically receive and admit high acuity Medicare patients, they do not bill the higher paid critical care codes as outpatient. As a consequence their average payment is lower.

A hospital can compute its own index by counting the number of its patients in each APC and multiplying the total in each APC by the national payment rates shown in Table 1. The total of the computed payment amounts for all four APCs divided by the total number of patients gives a case-weighted average payment amount for comparison. If a hospital’s computed average is significantly higher or lower than expected, the reason for the variance should be investigated.

Variations Among Individual Hospitals

Within each size grouping of emergency departments, the distribution of APC percentages and average payments are approximately normal, with some hospitals considerably higher or lower than average for each measure. Extreme variations can result from erroneous coding practices (e.g. using the same E&M code for most patients regardless of the services actually provided).

There were 10 hospitals with more than 90% of their patients classified to APC 610, the lowest level of evaluation and maintenance. While there could be operational reasons for such a low intensity, a hospital falling outside normal ranges should make certain that valid reasons exist. If patients are being routinely classified to the lowest APC regardless of actual circumstances, a hospital would be under-reimbursed.

Conversely, there were 20 hospitals with fewer than 2% of their patients classified to APC 610. Again, it is important to understand the reasons. If patients are being
erroneously classified to a higher range there could be a compliance problem related to over-reimbursement.

The following table further delineates the ranges for each APC. Hospitals were ranked from low to high in each category with the lowest percentage shown in the table as “min” (i.e. the minimum). The ranked hospitals were then divided into four quartiles with the highest percentage shown for each quartile. This table enables an individual hospital to compare its own experience with national experience. For example, if a hospital with 5,000 annual ED claims has 25% of its total claims in APC 610, it would be in the second quartile.

Table 7 – Quartile Ranges for the Percentages of E&M Claims by APC for 2004

<table>
<thead>
<tr>
<th>Annual ED Claims</th>
<th>APC 610 (low)</th>
<th>APC 611 (mid)</th>
<th>APC 612 (high)</th>
<th>APC 620 (critical)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quartile:</td>
<td>min</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>500-1,000</td>
<td>0</td>
<td>22</td>
<td>38</td>
<td>54</td>
</tr>
<tr>
<td>1,001 - 4,000</td>
<td>0</td>
<td>17</td>
<td>31</td>
<td>45</td>
</tr>
<tr>
<td>4,001 - 7,000</td>
<td>1</td>
<td>14</td>
<td>26</td>
<td>42</td>
</tr>
<tr>
<td>7,001 - 10,000</td>
<td>0</td>
<td>11</td>
<td>21</td>
<td>36</td>
</tr>
<tr>
<td>&gt;10,000</td>
<td>1</td>
<td>13</td>
<td>24</td>
<td>38</td>
</tr>
<tr>
<td>All Hospitals</td>
<td>0</td>
<td>16</td>
<td>30</td>
<td>45</td>
</tr>
</tbody>
</table>

Conclusion

This analysis of Evaluation and Maintenance coding appears to indicate that some hospitals may be over-coding or under-coding emergency department services. Claims data are useful in identifying potential problems, but do not consider operational circumstances that may cause variances. Hospitals should regularly review their own outpatient claims data in relation to the ranges in this study in order to determine whether there are situations that should be investigated. Systemic under-coding can lead to under-reimbursement. Systemic over-coding can be a compliance problem requiring immediate intervention and correction.
Variation in Coding of Evaluation and Management (E&M) Services by Hospital Emergency Departments

A study by:

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January 8, 2004
Variation in Coding of Evaluation and Management (E&M) Services by Hospital Emergency Departments

Summary

More than a year after implementation of the Medicare Outpatient Prospective Payment System there are unexpected variances in the assignment of E&M codes on emergency department claims. Hospital outpatient PPS claims were used to define normal Medicare payment levels and distributions of patients among various levels of E&M codes for calendar year 2002. Data for some hospitals indicate that there may be systematic undercoding or overcoding of emergency department encounters. Undercoding can result in lower levels of reimbursement. Overcoding can be a compliance problem requiring immediate intervention and correction. The findings of this study should be useful in helping a hospital to determine whether its E&M coding is within expected ranges.

Background

Medicare implemented an Outpatient Prospective Payment System (OPPS) for hospital outpatient services in 2000. Under this system a hospital is paid fixed rates for various Ambulatory Payment Classifications (APCs). The procedures detailed on a Medicare patient’s bill are grouped into these APCs in order to determine payment. Complete and accurate coding of procedures is therefore important in order to ensure that a hospital receives accurate payment.

This study focuses on the assignment of Evaluation and Management services (E&M codes) since they are used frequently and can be problematic. These codes reflect the extent of clinical staff (i.e. physician, technician, nurse, etc.) involvement with a patient and define APC payments ranging from $63 to $408 for the medical component of a hospital-based outpatient visit. However, coding guidelines for E&M codes are somewhat ambiguous for hospital use, and incorrect coding can result. This study assesses the potential prevalence of such errors by hospital Emergency Departments.

Sources and Limitations of Data

This study is based on Medicare PPS claims for hospital emergency department (ED) visits during calendar year 2002, as billed through 12/31/2002. Claims data were obtained from the Centers for Medicare and Medicaid Services (CMS) in two files:

- Hospital Outpatient Prospective Payment System (OPPS) Limited Data Set (LDS) for the nine months ending 12/31/2002 (Proposed 2004)
- Hospital Outpatient Prospective Payment System (OPPS) Select File for the twelve months ending 3/31/2002 (Final 2003)
These two files contain fee-for-service claims data for Medicare hospital outpatient bills. They were combined in order to cover the most recent twelve month period for which data are available. Note that all data obtained from CMS and used in this analysis are consistent with CMS Data Release Policies.

When reviewing this analysis and its findings, it is important to note that Medicare patients who are admitted to a hospital through its Emergency Department are not included in outpatient claims data. (Medicare does not allow hospitals to bill separately for outpatient services provided prior to an admission.) Therefore, admitted patients are excluded from this analysis. Furthermore, patients covered by a Medicare managed care plan also are excluded, since the CMS outpatient data include only fee-for-service claims. Thus, this analysis does not represent the entire population of Medicare ED patients.

Evaluation and Management Codes

Criteria for coding Evaluation and Management services are based on factors such as the detail of patient history, extent of patient examination, complexity of medical decision making, and whether the patient is critically ill or injured. Since E&M codes were originally designed for physician or professional services reporting, it is difficult to assign these codes in the hospital setting.

E&M services are grouped into four APC categories representing a range of resource consumption. The fiscal year 2002 definitions and national payment rates for these APCs are:

<table>
<thead>
<tr>
<th>APC</th>
<th>Description</th>
<th>Payment Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>610</td>
<td>Low level emergency visits</td>
<td>$62.61</td>
</tr>
<tr>
<td>611</td>
<td>Mid level emergency visits</td>
<td>$109.95</td>
</tr>
<tr>
<td>612</td>
<td>High level emergency visits</td>
<td>$177.65</td>
</tr>
<tr>
<td>620</td>
<td>Critical care</td>
<td>$427.59</td>
</tr>
</tbody>
</table>

Though criteria for the assignment of E&M codes in the hospital setting are currently ambiguous, CMS has announced intentions to publish more specific criteria early in 2004. (Physicians will be excluded from using the new criteria for their professional E&M coding.)

Hospital Categories
The acuity of patients (and their APC mix) may differ across hospital emergency departments according to factors such as:

- the characteristics of the population served
- the range and complexity of services offered
- hospital size and specialties
- referral relationships among hospitals in an area
- regional influences on healthcare
Therefore, to more accurately identify the typical distributions of ED patients by APC, hospitals were categorized according to their annual emergency department claims volume (i.e. the total number of claims with APCs 610, 611, 612, or 620). Hospitals with fewer than 500 claims during calendar year 2002 were excluded. It was felt that hospitals with fewer than 500 claims had only minor ED operations (i.e. fewer than two Medicare patients on average per day) and did not have sufficient volumes for analysis. The remaining hospitals are shown in Table 2.

### Table 2 – Distribution of Hospitals According to ED Volumes

<table>
<thead>
<tr>
<th>Annual Emergency Dept Claims</th>
<th>Number in Range</th>
<th>Total Number Claims</th>
<th>Average Number Claims</th>
</tr>
</thead>
<tbody>
<tr>
<td>500 - 1,000</td>
<td>181</td>
<td>133,603</td>
<td>738</td>
</tr>
<tr>
<td>1,001 - 4,000</td>
<td>1,093</td>
<td>2,882,777</td>
<td>2,637</td>
</tr>
<tr>
<td>4,001 - 7,000</td>
<td>1,043</td>
<td>5,656,606</td>
<td>5,423</td>
</tr>
<tr>
<td>7,001 - 10,000</td>
<td>641</td>
<td>5,346,714</td>
<td>8,341</td>
</tr>
<tr>
<td>&gt;10,000</td>
<td>760</td>
<td>11,226,936</td>
<td>14,772</td>
</tr>
<tr>
<td>TOTALS</td>
<td>3,718</td>
<td>25,246,636</td>
<td>6,790</td>
</tr>
</tbody>
</table>

For each volume category, the distribution of claims among the four APCs was examined:

### Table 3 – Distribution of E&M Claims According to Hospital Volume

<table>
<thead>
<tr>
<th>Annual Emergency Dept Claims</th>
<th>APC 610 (low)</th>
<th>APC 611 (mid)</th>
<th>APC 612 (high)</th>
<th>APC 620 (critical)</th>
</tr>
</thead>
<tbody>
<tr>
<td>500-1,000</td>
<td>35.8%</td>
<td>46.8%</td>
<td>15.3%</td>
<td>2.1%</td>
</tr>
<tr>
<td>1,001 - 4,000</td>
<td>32.9%</td>
<td>48.7%</td>
<td>16.8%</td>
<td>1.7%</td>
</tr>
<tr>
<td>4,001 - 7,000</td>
<td>28.7%</td>
<td>50.5%</td>
<td>19.1%</td>
<td>1.7%</td>
</tr>
<tr>
<td>7,001 - 10,000</td>
<td>25.9%</td>
<td>52.6%</td>
<td>20.3%</td>
<td>1.2%</td>
</tr>
<tr>
<td>&gt;10,000</td>
<td>23.0%</td>
<td>53.8%</td>
<td>21.9%</td>
<td>1.3%</td>
</tr>
<tr>
<td>Average</td>
<td>26.1%</td>
<td>52.2%</td>
<td>20.3%</td>
<td>1.4%</td>
</tr>
</tbody>
</table>

As might be expected, smaller emergency departments provided a higher proportion of lower intensity services (i.e. those hospitals with lower numbers of annual ED claims had a higher proportion of patients with APC 610 - the lowest level of physician evaluation and management). Conversely, larger emergency departments provided higher proportions of higher intensity services (i.e. APC 611 and APC 612).

It would seem logical to expect larger emergency departments to also provide higher proportions of critical services (i.e. APC 620). However, the data seem to indicate just the opposite. The reason for this is that critical patients are more often admitted in larger hospitals, and therefore do not appear in the outpatient data. On the other hand, critical patients are often transferred from smaller hospitals to larger ones (instead of being...
admitted to the smaller hospital). Consequently, such transferred patients do appear in the outpatient data for the smaller hospitals.

Using Average Reimbursement as an Index of Patient Mix

Medicare pays a fixed rate for each APC according to national payment rates that are updated periodically. Because these rates are based on relative costs, they are a good proxy for relative intensity of service among APCs. For payment purposes this rate is normally adjusted to account for wage differences among hospitals in different geographic areas. (Actual payment amounts for E&M procedures might also be reduced when bundled with other procedures performed.) For this study, however, we used unadjusted national rates to calculate and compare average payment among hospitals. This average payment based on national rates serves as an acuity index that reflects the distribution of patients among the various APCs.

Table 4 – Average E&M Payment (based on national payment rates)

<table>
<thead>
<tr>
<th>Annual Emergency Dept Claims</th>
<th>Average Payment (national rate)</th>
</tr>
</thead>
<tbody>
<tr>
<td>500-1,000</td>
<td>$110</td>
</tr>
<tr>
<td>1,001 - 4,000</td>
<td>$111</td>
</tr>
<tr>
<td>4,001 - 7,000</td>
<td>$115</td>
</tr>
<tr>
<td>7,001 - 10,000</td>
<td>$115</td>
</tr>
<tr>
<td>&gt;10,000</td>
<td>$118</td>
</tr>
<tr>
<td>Average</td>
<td>$117</td>
</tr>
</tbody>
</table>

As might be expected, higher volume emergency departments treat more high-acuity patients and therefore have a higher average payment. A hospital can compute its own index by counting the number of its patients in each APC and multiplying the total in each APC by the national payment rates shown in Table 1. The total of the computed payment amounts for all four APCs divided by the total number of patients gives a case-weighted average payment amount for comparison.

Variations Among Individual Hospitals

Within each group of emergency departments, the distribution of APC percentages and average payments are approximately normal, with some hospitals considerably higher or lower than average for each measure. Extreme variations can result from erroneous coding practices (e.g. using the same E&M code for most patients regardless of the services actually provided). Table 5 shows ranges for 90% of hospitals in each category, excluding the highest 5% and the lowest 5%.
Table 5 – Ranges for 90% of hospitals

<table>
<thead>
<tr>
<th>Emergency Dept Claims</th>
<th>APC (low)</th>
<th>APC (mid)</th>
<th>APC (high)</th>
<th>APC (critical)</th>
<th>Average Payment (nat rate)</th>
</tr>
</thead>
<tbody>
<tr>
<td>500-1,000</td>
<td>7-73%</td>
<td>20-72%</td>
<td>3-5%</td>
<td>0-7%</td>
<td>$82-144</td>
</tr>
<tr>
<td>1,001 - 4,000</td>
<td>5-74%</td>
<td>16-78%</td>
<td>2-43%</td>
<td>0-9%</td>
<td>$85-148</td>
</tr>
<tr>
<td>4,001 - 7,000</td>
<td>7-59%</td>
<td>29-74%</td>
<td>4-42%</td>
<td>0-6%</td>
<td>$88-143</td>
</tr>
<tr>
<td>7,001 - 10,000</td>
<td>5-54%</td>
<td>32-74%</td>
<td>4-43%</td>
<td>0-4%</td>
<td>$93-139</td>
</tr>
<tr>
<td>&gt;10,000</td>
<td>5-47%</td>
<td>33-74%</td>
<td>5-43%</td>
<td>0-5%</td>
<td>$96-143</td>
</tr>
<tr>
<td>Average</td>
<td>6-59%</td>
<td>28-73%</td>
<td>4-40%</td>
<td>0-6%</td>
<td>$89-141</td>
</tr>
</tbody>
</table>

Hospitals outside these ranges deserve further investigation. For example, there were eight hospitals with more than 90% of their patients classified to APC 610, the lowest level of evaluation and maintenance. While there could be operational reasons for such a low intensity, a hospital falling outside normal ranges should make certain that valid reasons exist. If patients are being routinely classified to the lowest APC regardless of actual circumstances, a hospital would be underreimbursed.

Conversely, there were nineteen hospitals with fewer than 2% of their patients classified to APC 610. Again, it is important to understand the reasons. If patients are being erroneously classified to a higher range there could be a compliance problem related to overreimbursement.

Actual case studies conducted by The enVision Group, Inc. show similar trends in their outcomes reporting. enVision concurs that hospitals should conduct periodic validation studies to ensure proper coding, charging and reporting of outpatient services to reduce both risk and liability in addition to proper payments.

Appendix A provides a table that further delineates the ranges for each APC. Hospitals were ranked from low to high in each category with the lowest value shown in the table as “minimum.” The ranked hospitals were then divided into five quintiles with the highest value shown for each quintile. This table enables an individual hospital to compare its own experience with national experience. For example, if a hospital with 5,000 annual ED claims has an average national payment amount of $125 it would be in the fourth quintile representing the experience rate of 80% of the nation’s hospitals.

Conclusion

This analysis of Evaluation and Maintenance coding shows that some hospitals may be overcoding or undercoding emergency department physician services. Claims data are useful in identifying potential problems, but do not consider operational circumstances that may cause variances. Hospitals should regularly review their own claims data in relation to the ranges in this study in order to determine whether there are situations that should be investigated. Systemic undercoding can lead to underreimbursement. Systemic overcoding can be a compliance problem requiring immediate intervention and correction.
Endnotes

1 Final Rule: Medicare Program; Changes to the Hospital Outpatient Prospective Payment System for Calendar Year 2002 (CMS-1159-F2), Addendum A.
# Appendix A - Quintile Ranges for the Distribution of E&M Claims According to Hospital Volume

<table>
<thead>
<tr>
<th>Quintile Points</th>
<th>Min 1 2 3 4</th>
<th>Max</th>
<th>Min 1 2 3 4</th>
<th>Max</th>
<th>Min 1 2 3 4</th>
<th>Max</th>
<th>Min 1 2 3 4</th>
<th>Max</th>
<th>Min 1 2 3 4</th>
<th>Max</th>
</tr>
</thead>
<tbody>
<tr>
<td>Annual ER Dept Claims</td>
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<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>500-1,000</td>
<td>0 19 29 40 53 100</td>
<td>0 32 44 51 60 86</td>
<td>0 7 10 15 22 100</td>
<td>0 0 0 2 4 22</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1,001 - 4,000</td>
<td>0 17 26 37 48 97</td>
<td>0 37 45 53 61 93</td>
<td>0 7 12 17 24 76</td>
<td>0 0 1 1 3 26</td>
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<td></td>
</tr>
<tr>
<td>4,001 - 7,000</td>
<td>0 14 22 31 43 94</td>
<td>0 38 46 54 63 88</td>
<td>0 9 14 20 27 79</td>
<td>0 0 1 1 2 30</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>7,001 - 10,000</td>
<td>0 12 19 28 39 96</td>
<td>0 41 49 56 64 94</td>
<td>0 9 16 22 30 78</td>
<td>0 0 0 1 2 14</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt;10,000</td>
<td>0 11 18 25 35 93</td>
<td>0 42 50 58 64 91</td>
<td>0 11 18 24 31 69</td>
<td>0 0 0 1 2 26</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All Hospitals</td>
<td>0 14 22 31 43 100</td>
<td>0 38 47 55 63 94</td>
<td>0 8 14 20 28 100</td>
<td>0 0 1 1 2 30</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Quintile Points</th>
<th>Min 1 2 3 4</th>
<th>Max</th>
<th>Min 1 2 3 4</th>
<th>Max</th>
<th>Min 1 2 3 4</th>
<th>Max</th>
<th>Min 1 2 3 4</th>
<th>Max</th>
</tr>
</thead>
<tbody>
<tr>
<td>Annual ER Dept Claims</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>500-1,000</td>
<td>63 95 103 112 122 185</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1,001 - 4,000</td>
<td>63 96 106 114 123 207</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>4,001 - 7,000</td>
<td>63 100 109 118 127 195</td>
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<td></td>
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<tr>
<td>7,001 - 10,000</td>
<td>65 102 111 119 128 164</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>&gt;10,000</td>
<td>66 105 113 121 129 237</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All Hospitals</td>
<td>63 100 109 118 127 237</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
avoiding fraud risks associated with EHRs

An electronic health record can reduce a healthcare provider's exposure to risk posed by the fraudulent use of healthcare data, but only to the extent that the provider has established proper controls within the system.

Fraud in the healthcare industry is a large and growing problem. and with the expanded use of electronic media for healthcare transactions, the pace at which the problem is increasing may well pick up substantially. Faced with this growing problem, potentially exacerbated by the use of electronic health record (EHR) technology, healthcare organizations would do well to proactively seek solutions. It is possible that when used properly, EHR technology could actually serve as a layer of protection against fraudulent activity. But if implemented without proper controls, EHR systems could make it easier for bad actors to perpetrate fraud in a healthcare organization's name.

EHR technology can be used in the conduct of fraudulent actions through misuse of data captured in the EHR to prepare false claims for payment. Such actions could be committed by anyone within the provider organization who has access to the system. Conversely, the power of the EHR can be harnessed to prevent fraud through implementation of control mechanisms that protect data that could otherwise be used to perpetrate fraud, and that validate data used for legitimate provider reimbursement.

Healthcare providers that do not implement strong controls over the access to and use of EHR technology may unwittingly be subject to prosecution by authorities for a fraudulent billing action. Hence, it is critical that the EHR adopter examine both the EHR application and the associated business practices to eliminate such risks to the extent possible. By implementing appropriate controls, a provider demonstrates its honest intent in the event of a possible billing or collection error—potentially eliciting a more favorable view from investigators and prosecutors in such an event.
Although no current or recent prosecutions cite EHR technology as a contributor to a fraudulent action, the data collection is still evolving. The perpetration of a fraud entails a need (or desire) for additional money, an opportunity to defraud (through lax controls), and then the action itself. EHR technology can represent the opportunity for fraudulent action—something not always specifically cited in a prosecution action.

**Fraud Risks Associated with EHR Use**

Fraudulent use of EHR technology can be grouped into two broad areas of concern:

> Inappropriate billing by providers, including unbundling of services or the inaccurate description of clinical services provided to a patient during a legitimate patient encounter

> Inappropriate access by a system user resulting in modification of existing patient data to create a false claim for services.

(These areas are described in two separate reports issued by RTI International, an independent not-for-profit research institute, for the Office of the National Coordinator for Health Information Technology [ONC] of the U.S. Department of Health and Human Services [HHS] and by Kroll Fraud Solutions, a global risk consulting company, for the Health Information Management Systems Society [HIMSS].)\(^a\)

**Inappropriate billings.** Providers may create inappropriate billings for services as a result of how the services are described using the EHR system. In the absence of any validating controls to ensure each service is correctly described in the broader context of the patient’s presenting condition, medical history, and generally accepted billing protocols, erroneous data could be compiled and integrated into claims for reimbursement. In particular, the use of standardized templates in an EHR system could lead a provider to commit inadvertent errors in documentation if the provider does not thoroughly review and complete the template for each patient in every clinical encounter. Errors in documentation also can occur through use of clinical notes, where standard language and phrases are added to a clinical note through selection of menu choices in the EHR user interface.

That is not to say that such errors could never exist in a paper-based system or one using dictated notes. However, the fact that clinical documentation is intended to seamlessly feed data to a provider billing application without human intervention presents a somewhat greater risk of an error in documentation becoming an error in billing without detection.

The use of default templates, standardized notes, copy/paste, defaults forward, and import functions are additional examples of timesaving functions critical to user adoption of EHR technology. Yet, as noted in the RTI report, those benefits also open the EHR application to potential fraudulent use without proper edits, controls, or user attentiveness to the task at hand. As a result, the very functionality hoped to improve accuracy of documentation and efficiency of clinical operations could create a potential legal hazard to the provider if controls to mitigate risk are not built into the EHR application or in supporting business practices.

**Inappropriate access.** Inappropriate access to an EHR system poses the risk of users creating false
claims for services using existing patient records to generate billings for “phantom” patient encounters. Employees who have access to EHR modules and billing modules in a provider entity could be able to enter fraudulent encounters, generate billings, and then delete documented encounter data (thereby “covering their tracks”).

A basic tenet of many business processes is one of segregation of duties where employees in a business have limits placed on job functions to prevent potential misappropriation of cash and other assets. Yet according to a 2008 article by Donald W. Simborg, MD, provider offices often represent an exception to this practice: Employees of providers often may cover multiple functions, leading to increased risk from conflicting duties or password sharing (“Promoting Electronic Health Record Adoption. Is It the Correct Focus?” Journal of the American Medical Informatics Association, March-April 2008, pp. 127–129.) This situation creates a fertile ground for scenarios to develop in which employees can access clinical documents, make entries to a false clinical record, and then generate a billing for payment that can be fraudulently directed to that employee’s benefit. This risk could be heightened in a situation where the EHR and patient accounting functions have separate applications and vendor service contracts. b

Notwithstanding the criminal intent inferred by such actions, a further complication for the

b. For discussions of this risk, see Revenue Cycle Management Guide, Salt Lake City, Utah: Ingenix Publishing Group, 2006; and Fraud Examiner’s Manual, Austin, Texas: Association of Certified Fraud Examiners, 2008.

**Fraud in Health Care: The Scope of the Problem**

Healthcare services provided in the United States resulted in over $2.26 trillion in payments for more than four billion health insurance benefit claims in 2007, according to a 2008 Consumer Alert from the National Health Care Anti-Fraud Association (NHCAA). A industry with that amount of money flowing through it is almost certain to attract the attention of unscrupulous people intent on some act of dishonesty or outright fraud. Meanwhile, the extent of controls over the evaluation of provider claims for payment is being challenged, as insurers are pressured to expedite payments and use automated payment processes (Busch, R., Healthcare Fraud: Auditing and Detection Guide, Hoboken, N.J.: John Wiley & Sons, Inc; 2008). This situation could lead to an increased likelihood of fraudulent claims going undetected.

Although estimates vary as to the extent of fraudulent activity in the healthcare industry, the very size of the industry itself suggests that the risks of loss to fraud are significant. The NHCAA’s Consumer Alert also presented a “conservative estimate” that 3 percent of all healthcare spending (an amount totaling $68 billion) was diverted to fraudulent ends.

In 2008, the Association of Certified Fraud Examiners (ACFE) presented some collected quantitative estimates of the value of fraudulent activity in health care:

- About $133 billion, or 7 percent of all payments governed by the Centers for Medicare & Medicaid Services (CMS), were disbursed improperly due to the filing of illegitimate claims (CMS estimate).
- An estimated $50 billion (10 percent) of payments made by The Blue Cross and Blue Shield (BCBS) associations estimate were for fraudulent payments (BCBS estimate).
- $100 billion in other private insurer or patient payments (20 percent of that payment population) were for some form of improper billing (NHCAA estimate).

Despite the extent of this fraudulent activity, however, healthcare provider awareness of the risk posed by fraud is perhaps less than it should be. A recent survey conducted for the Health Information and Management Systems Society indicated a higher degree of
provider—noted in the RTI and Kroll reports for ONC and HIMSS, respectively—arises from a potential violation of HIPAA should EHR data be shared with parties outside of the organization to generate fraudulent bills. Employees with legitimate access to EHR data could copy such data and share it with parties outside of the provider organization for use in fraudulent billing schemes. Although the provider in this case may not have perpetrated a fraud, the associated violation of HIPAA is an important risk concern.

**Recommended Risk Mitigation Steps**

No fraud control effort or internal control mechanism is foolproof or capable of preventing every possible act of fraud. If employees with properly segregated provider and provider staff awareness of and attention to risks associated with a violation of the Health Insurance Portability and Accountability Act than to the risks of a fraudulent act.

Healthcare provider organizations face a variety of different types of fraud risk:

- **Patient fraud**—insured patients submitting false claims for reimbursement or allowing others to use benefits for payment for services
- **Provider employee fraud**—employees of provider organizations using data obtained through employment to fraudulently obtain payments from insurers
- **Provider billing fraud**—providers submit claims for services not actually provided, including falsifying data submitted as a part of a claim for payment

- **Payer fraud**—insurance plan administrators modifying submitted claim data and applying incorrect payment amounts to fraudulently altered claims

Despite the extent of this risk, however, it is important to note that not all payments for healthcare services that are made in error are a result of fraud. Payment errors can arise simply from mistakes in coding or description of services, data errors, or user confusion over appropriate coding procedures to apply. But the current regulatory environment essentially presumes guilt by a provider for submittal of a false claim for payment. Today, that presumption is significant enough that even the identification of a pattern of billing errors or inaccurate claims may be considered an action subject to prosecution by authorities.

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admit a patient should not be able to process any additional transactions on a patient account and should not handle payments received on a patient account. System-based controls can enforce those process controls through assignment of specific roles to a user and preventing user transactions that are outside of assigned roles.

As a practical matter, a single provider office or small rural facility may not be in a position to hire the extra staff needed to properly separate admitting, patient record updates, and billing/collection functions. In such a circumstance, mitigating controls such as random unannounced audits by an outside party, outsourcing of billing/collection functions, or random follow-up with patients to verify encounters and services billed by the provider may be useful to deter a potential fraudulent act.

Both internal and system-based controls can be easily integrated into the control framework of an EHR installation. Specifically, user access to set up a patient record in the EHR system should be segregated from user access to make clinical entries on that patient record. To implement such controls, the provider would require an EHR application with user-specific role definitions.

RTI International in its 2007 work commissioned for HHS’s ONC offered 14 recommendations that, if implemented, would ensure data accuracy and establish reasonable controls against fraud in an EHR. The recommended controls are as follows.

1. **Audit functions and features.** This control includes creating internal audit trails that capture types of user accesses, by user, with specifics of the time, date, and location of access.

2. **Provider identification.** Providers with access to enter clinical data should be discretely identified either by national provider identifier or some other unique identifier to segregate transactions in the EHR clinical history.

3. **User access authorization.** The EHR should include functionality to discern users and prevent unauthorized user entry by maintaining robust logon credentials with a user identification and password.

4. **Documentation process issues.** All encounter notes should be date/time stamped and be able to be entered by a variety of means, including keyboard entry, speech, automated defaults, copy/paste from other notes, and import from outside sources.

5. **Evaluation and management (E&M) coding.** The system should prompt users to validate entries that support assignment of E&M codes that would later be used in billing.

6. **Proxy authorship.** The identity, time/date, and content of any transactions entered on behalf of a licensed provider should be clearly documented.

7. **Record modification after signature.** The provider should retain “before” and “after” copies of record elements that were modified after closing of a patient encounter by the provider’s electronic signature.

8. **Auditor access to patient records.** Payer auditors’ access to the system should be limited to view-only access for review of records associated with a given patient covered by that payer.

As the value of payments for healthcare services increases and the use of EHR technology expands, so too does the risk of additional fraud losses to the healthcare industry.
Providers may be held accountable for innocent errors in documentation or coding just as much as they would for overt actions of fraud in our current regulatory environment. Additional fraud losses to the healthcare industry. Providers may be held accountable for innocent errors in documentation or coding just as much as they would for overt actions of fraud in our current regulatory environment. For this reason, fraud prevention actions become more important when providers implement EHR technology. There are clear steps that providers should take with both general business processes and EHR system functionality to mitigate fraud risk exposures in the healthcare provider operation.

The 2010 healthcare reform legislation raises the stakes for EHR operations even more. Much of the operational change in that legislation focuses on improving efficiency in healthcare delivery through use of accountable care organizations (ACOs). The medical home concept upon which the ACOs are based relies on EHR technology for improving exchange of medical data among ACO providers. The ACO concept should further expansion of EHR use—and with it the risk of illicit action. The increased risk calls even more for the implementation of EHR technology with proper business controls.

About the author

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Preparing for Even Greater Risk
Healthcare fraud presents a large and growing risk to the government, insurers, and individuals in the United States. As the value of payments for healthcare services increases and the use of EHR technology expands, so too does the risk of
<table>
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(2002 level for hospitals only)
Two of the most critical technological challenges the US is facing are the formal development of software and the formal development of web knowledge. By formal I mean the use of mathematics to prove that software is correct and to prove that correct conclusions are derived from web knowledge. Our entire economy is run by software and business decisions are increasingly based on web knowledge. Continuing to base our actions on unproven software and unproven knowledge is a danger to our economical competitiveness and to our national security.

There are visible efforts within the US, the European Community, Russia, and China, to make headway in these two areas. We cannot afford to lose this race. It is not the physical access to our critical national buttons that is our main concern, it is the fact that by exploiting unproven software and unproven knowledge, entire networks that lead to these buttons can be paralyzed or hijacked.

In the US, almost all the related formal work in these two areas is confined to universities. There is a huge gap between university research and the necessary translation of this research into industrial applications. We have initiated a program of study at the University of California Berkeley that attempts to bridge this gap. The program is described at http://extension.berkeley.edu/spos/pdf/fsd_presentation.pdf. The goal is to raise the level of mathematical knowledge among working software professionals in Silicon Valley, our largest concentration of engineering and entrepreneurial talent. We intend to fully leverage the computational intuitions of software professionals and teach the needed mathematics via logic and computation in a laboratory environment, using computing systems instead of blackboard or dry presentations. It is a very ambitious program and it would need resources far beyond what I can provide alone.

It's hard to imagine a better response to President Barack Obama's call to win the future than a determined effort to raise the mathematical foundations of software development and of web knowledge development. It would be a remarkable achievement of this Administration if it launched a Manhattan-style project aimed at solving these two most pressing technological challenges of our time. They cannot be solved through the fragmented and timid approaches currently in use.

Your comments are appreciated,

dr. Adrian Zidaritz  
zidaritz@berkeley.edu
From: Krishna Murali Brahmandam [mailto:krishna@proheamon.com]
Sent: Monday, February 07, 2011 8:26 AM
To: 'lander@broadinstitute.org'
Cc: 'jlevin@stanford.edu'; 'wpress@cs.utexas.edu'; 'jhalamka@caregroup.harvard.edu'
Subject: extremely stupid - FW: nothing new after so much time and money
Importance: High

To say the least, REPORT TO THE PRESIDENT REALIZING THE FULL POTENTIAL OF HEALTH INFOMATION TECHNOLOGY TO IMPROVE HEALTHCARE

FOR AMERICANS: THE PATH FORWARD - is very silly and insults the intelligence of the average American! President's Council of Advisors on Science and Technology should have done much better than this. Let me know if you need help with making health data interoperability really get implemented (Say NO to IHE XDS 😊) and also become truly useful and cost effective. We don’t need no European XDS interoperability! Please forward to your peers and superiors too. Thanks. Get help and get interoperable. 😊 Communication is the best way to solve this problem. Hope to hear from you. The report says these below for example.

1. “Health information technology can allow clinicians to have real-time access to complete patient data, and provide them with support to make the best possible decisions” --- Clinicians don’t want to get or give real-time access to complete patient data and they don’t want to make the best possible decisions! Clinicians are self-centered and want real-time bank deposited payment data and want to make best possible decisions to avert malpractice suits.

2. “limitations of SOAs” --- does it mean ONCHIT will fire its SOA architect? 😊

3. The concept of DEAS is nothing new. Some people including myself knew it and worked on it with USHIK, AHRQ in 2008-09. The problem was that USHIK, under misguidance from Clancy messed up and took in too much junk, hence with was called the US Junk Health Information Knowledgebase (USJIHK). That’s a clue right there.

4. There is no one person in the US called ‘Patient’, one person called the ‘Payer’, and another person called ‘Provider’! The words Patients, Providers, and Payers are mentioned over 100 times each in the report. It is extremely stupid for those in teaching / IT field to do this kind of nonsense. Is this what is taught to students? This is pathetic and shameful. I feel so sick reading this kind of reports.

5. Money in health industry, specifically the CMS, is nobody’s money. So nobody cares what really happens.

6. It is hilarious how the PCAST came up with nothing new after so much time and money.

With best regards,
Krishna Murali Brahmandam, Managing Director
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"Ron Stone" <gigaeon@gmail.com>

RE: metrification and Education & Economy Connection (gigaeon@gmail.com)

Date: Thu, February 3, 2011 4:14 am

To: globaleconomy101@gmail.com

Cc: VikingWebSupport@viking.com, owm@nist.gov, dkaufmann@brookings.edu, srose@usd259.net, michael.d.berkey@dowjones.com, rvineyard@doe.nv.gov, info@clintonglobalinitiative.org, hegele_n@cde.state.co.us, dtsine@ostp.eop.gov, ggallagher@nd.gov, davidp@ccsso.org, luke.h.lee@gmail.com, ssparris@alsde.edu, bixby@ci.manhattan ks.us, dfrendak@astc.org, science_policy@aaas.org, pcordeiro@broadcenter.org, bbosworth@brookings.edu, dward@wabonssee.edu, D eirdre@excelled.org, kathy.petosa@iowa.gov, jennifery@thehill.com, copyright.notice@ft.com, m.hutchison@sd5.k12.mt.us, bmelton@putnamcityschools.org, mbaily@brookings.edu, bjones@brookings.edu, Cartwright_B@cde.state.co.us, jana_rowland@sd2.state.ok.us, ellen.ebert@k12.wa.us, pat.naughtin@metrificationmatters.com, aglopez@comcast.net, ericcantor@mail.house.gov, nmontoya@broadcenter.org, legaffairs@nsta.org, dlong@vernier.com, communications@brookings.edu, elsmith@astc.org, rhinoxan@cox.net, Jennifer62@q.com, feroz.mohmand@live.com, inquiries@nctm.org, submission@prosyn.org, nctm@nctm.org, jkaufmann@usd.edu, msmith@americanprogress.org, kjrome@gmail.com, bmupanduki@cde.ca.gov, Arthur.Estopinan@mail.house.gov, bkatz@brookings.edu, jbeek@fuse.net, hillger@cira.colostate.edu, rmorley@thetrumpet.com, jwilliamson@pierce.edu, info@aaeteachers.org, zachary.kurz@mail.house.gov, info@foreignpolicyi.org, pwhite@ti.com, mike_johanns@johanns.senate.gov, bwojnowski@gmail.com, irene.pickhardt@tea.state.tx.us, communications@ccsso.org, abruixjr@lycos.com, latasha.fisher@fdoe.org, GrantsRep@nmsta.org, ehall@k12.al.us, beth_thomason@gfps.k12.mt.us, jbutte@usd489.com, alooney@brookings.edu, NCTC@ostp.gov, feedback@edutopia.org, kblomberg2@comcast.net, ahammersley@usd4.org, AlbuquerqueRep@nmsta.org, wpic@worldpolicy.org, jon.hilsenrath@wsj.com, worldservice.moderation@bbc.co.uk, doug.ray@tuscaloosanews.com, doug@radiosbag.com, cwellisz@bloomberg.net, jack.gerlovich@drake.edu, jucuzoglu@broadcenter.org, bcunning@aapt.org, ChristyH@excelled.org, jegreco@cde.ca.gov, padamas@fh.su.edu, pblustein@brookings.edu, development@aaas.org, kcrawford@mt.gov, commission@fc.eop.gov, wllamsn181@gmail.com, khollweg@stanfordalumni.org, arivlin@brookings.edu, ikatz2@bloomberg.net, OGrady@wsj.com, john.lyons@wsj.com, johnlorenz@sbcglobal.net, gilda.wheeler@k12.wa.us, firstlady@mt.gov, editors@gowbrc.com, chapters@nsta.org, ewoeten@aaas.org, igraytock@nea.org, msjensen@umn.edu, bbailey@mercurynews.com, m membership@aaas.org, muhammad@svfoundation.org, paulap@newsmax.com, altask@yahoo.com, worldhaveyoursay@bbc.com, mmcombec@sbglobal.net, senator_bingaman@bingaman.senate.gov, TheSI@nist.gov, ADE, Communications@arkansas.gov, africa@sis.org, csandler@umich.edu, lacey.wieser@azed.gov, equscied@defuniak.com, jim.woodland@nebraska.gov
v, rnelson@alsde.edu, ehr@aaas.org, sricks@alsde.edu, gtaggart@fhsu.edu, mlongshore@broadcenter.org, ken.obrien@slc.k12.ut.us, ezra.steinberg@comcast.net, twillard@aaas.org, susan.fitzpatrick@thomsonreuters.com, kcheesma@capital.edu, wsj.ltrs@wsj.com, vansickle@cofc.edu, bmelton@oklomascienceteachersassociation.org, DeborahL.T@aal.com, kamckee@blankparkzoo.org, pcast@ostp.gov, mpidig@yahoo.com, jmorton@alsde.edu, mechtly@illinois.edu, manny@svefoundation.org, ejdionne@washpost.com, jfreed@msde.state.md.us, NewDesign@vocanews.com, skoba@cox.net, bunny1991@aal.com, editor@roubini.com, mark.little@bvst.org, bradley@brookings.edu, jmsteele9027@sbcglobal.net, LasCrucesRep2@nmsta.org, custserv@enasco.com, klein_t@cade.state.co.us, wanthonis@brookings.edu, bboggs@milecity.k12.mt.us, letters@pbropost.com, jwilhelm@bluevalleyk12.org, HomeschoolRep@nmsta.org, oped@nytimes.com, jdrellis@ku.edu, dry@attali.com, tamar@ips-dc.org, JimF@metricmethods.com, james@svefoundation.org, mmaxon@ostp.eop.gov, SorensKH@arc.losrios.edu, ros.atkins@bbc.co.uk, rschoen@lsi.fsu.edu, mouldingb@ogdensd.org, jtugeel@mmusa.org, executive@nsta.org, scott@ncse.com, rebecca.braaten@polk-fl.net, jswords@mcn.net, cbradford@brookings.edu, ssmith@sde.idaho.gov, mgsromoko@q.com, webmaster@nga.org, pleningerc@havre.k12.mt.us, Officers@sdsca.org, secretary@psupen.psu.edu, ombudsman@washpost.com, eo@aapt.org, dbyers@csginc.us, aili@brockings.edu, eed.webmaster@alaska.gov, mccomas@uark.edu, listadmin@nsta.org, kumashiro@antioppressiveeducation.org, cynde_jacobson@gfps.k12.mt.us, smcdonald.kats@gmail.com, yvette.mcculley@ioaw.gov, harkinintern@helpсенат.gov, ltiuchen@uaofsmith.edu, jimhoagland@washpost.com, baselinescenario@gmail.com, hussain.rahimi@gmail.com, germainradio@gmail.com, webeditors@epe.org.jim@schoolfoundations.org, AlbuquerqueRep2@nmsta.org, jonathan.wesman@wsj.com, tmontoya@msde.state.md.us, dbredthauer@fms.k12.nm.us, jverle@educ.state.wy.us, r.douglas@exploratorium.edu, ccrowl@cede.ca.gov, dfrench@okstate.edu, emscurric@mil.nysed.gov, troe399@ruraltel.net, damian.paletta@wsj.com, mkrehbiel@ksde.org, speakerboener@mail.house.gov, spattick@cfr.org, tlford@iu.edu, Mward@alsde.edu, kpopham@belgrade.k12.mt.us, ehessler01@hamline.edu, dbarnes@ksde.org, mdavies@emporia.edu, biologycctrack@hotmail.com

TO: a rather large number of Cc addressees (per Tim W of Brookwood AL):

i presume that recipients of this e mail amongst the large number of Cc addressees have an interest in matters of metrification to issues of both education and economy.

should this message have been regarded as unsolicited or unwanted, then you can simply delete or do nothing and Ronald L Stone of Hayward, California USA won't further use or share the replied e mail address. (Ron's mobile phone number [as answered in a California Pacific time zone] is however available to interested parties upon request.)

alternatively, interested parties can OPT IN to further e mail communications about BEST PRACTICES FOR METRIFICATION by replying to Ron at gjqaeon@gmail.com with a subject keyword METRIC or METRICATION.

thanks very much for interest in recognizing the importance of matters of metrification to issues of both education and economy!
DISCLOSURE: as of this posting, Ron, who elects to discuss information about
metrical on a nonpartisan basis, is not registered as a lobbyist in any
jurisdiction. nothing in this e-mail message is intended to create a
lobbying relationship. addressees are however advised that certain
interactions may call for the registration of a lobbying activity.

best wishes to

go metric!, and

best regards,

Ron

On Wed, Feb 2, 2011 at 2:19 PM, <globaleconomy101@gmail.com>
> wrote:

> I've shared The Education & Economy
Connection<https://docs.google.com/document/d/1y82bWZvYjFpyCii-
OdMmbcj CIKchbo61vqfyrLQTS0/edit?hl=en>
> Click to open:
> The Education & Economy
Connection<https://docs.google.com/document/d/1y82bWZvYjFpyCii-
OdMmbcj CIKchbo61vqfyrLQTS0/edit?hl=en>

> 31 Jan 2011
>
>
> A sustainable economy is driven by technological and scientific innovation
> and creativity. The good paying jobs will also come from new industries
> based on new technologies. To be competitive on the local and global stage
> requires academic excellence. If a state is stagnant and if it does not
> pursue advancements and instruction in the sciences, then its economy will
> ultimately decline.
>
>
> The US is at this fork in the road now. One way leads to sustainable
> economic recovery for the long-term, the other way leads to failure and a
> dependent third world status. Which do you prefer? What must be done to put
> us on the right path?
>
>
> We must devote resources to scientific and technological Research &
> Development, and to educating our children in the foundations of the
> sciences, math and engineering. The educational transformation must begin
in Kindergarten and continue through the twelfth grade and beyond. Only
then will we see a sustainable economic recovery for the US. Only then will
we create the new high tech good paying jobs our people need. If we are
serious about our future, then we must invest in R&D and Education in the
US
and in our state and county. We must have a vision beyond ourselves and
our
myopic self-interests.

New technologies, driven by advances in the sciences, which in turn is
propelled by a sound educational foundation, is our best hope for a
sustainable US economy. If we do nothing, if we just throw up our hands,
then we will surely fall further behind. As the world races past the US in
the sciences, math and reading skills, and in their commitment to R&D, then
the US must find those things that will differentiate it from the rest of
the planet.

Our world is truly global, and there is no going back, so what will make us
stand out among equals? What new skills must we teach our children to
foster and attract new industries and new businesses and the development of
new technologies? Are there any obstacles and hurdles standing in the way of
producing the successful and educated children of tomorrow?

One such hurdle is our use of the imperial English measurement system.
Businesses that operate around the world, and industries that are connected
to the sciences, which is just about everything today, such as materials
sciences, the medical field, nursing, pharmacies, biotechnology, chemistry,
physics, aeronautics, astronautics, telecommunications, the internet, R&D
facilities at the university, corporate and government level, as well as the
US government, and many others, use the SI metric system for its ease of use
and simplicity. Why are we the people not using the SI Metric system?
Dual
measurement instruction in the classroom and around the nation is an attempt
at procrastination and a waste of time. We need to be teaching and using
metric only. This is one obstacle we can and should fix for the sake and
future of our children and grandchildren.

Tim Williamson

Brookwood, Alabama, USA

1-205-765-6090
Ron Stone

______________________________
disclaimers or other restrictions may apply to this message.

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Attachments:
untitled-[2]
Size: 11 k
Type: text/html

From: "Bruce Wilder" <bwild@interprofessional.com>
Subject: Comment on PCAST Report on HIT, Dec. 2010
Date: Tue, February 1, 2011 10:23 am
To: pcast@ostp.gov

I would like to provide comments on the recent PCAST report, President’s Council of Advisors on Science and Technology /Report on Health Information Technology:/ /Calls for Adoption of Universal Exchange Language to Mobilize Data, Improve Healthcare, Enhance Privacy, and Cut Costs./

Overall, I find it to be an extremely valuable contribution. I do, however, have a concern that I wish to convey to you.

There is only a single reference to open source, and only in a statement that the VistA is not "flexible," made without further comment.

On page 53 the authors note "[The] route to interoperability does not mean that every provider has to adopt a standard health record format or reconfigure its approach to inputting and managing patient records," but does not further discuss whether such an environment would be undesirable.

It is astonishing to me that the role that an open source system could play in achieving the goals of the report's recommendations was not considered in the report, especially since there have been previous attempts to introduce open source into the debate about how to best achieve an interoperable national health infrastructure (See the attempts by Dr. David Brailer, the first ONC, in 2005 [1] and H. 6898 [2] introduced into the 110th Congress, but strongly opposed by the Health Information Management Systems Society [HIMSS]). Interestingly, the issue of open source in HIT was explored in detail in an earlier white paper published by HIMSS in June, 2008. [3]
The American Medical Association adopted policy in June, 2009 (H-478.992 OPEN SOURCE CODE ELECTRONIC MEDICAL RECORDS): "Our AMA supports law and public policy that would provide an open source electronic health record that meaningfully represents the interests of physicians and their patients, that embodies an open standards platform that is both interoperable at large and supports diverse substitutable software applications based on open or proprietary code, and will work with the Department of Health and Human Services and other agencies to implement this policy. (Res. 218, A-09)."

A more recent report has examined the potential role that an open source system, such as VistA, could play in the implementation of a national HIT infrastructure, along with the analysis of present barriers and ways to overcome them. [4]

If nothing else, it seems to me, the model for open source ought to be given serious consideration, especially in view of the government's serious budgetary problems, the public's worries about the cost of health care, and the well-known struggles that many health care providers, both physicians and institutions, are having with their bottom lines. I strongly urge that the value of open source in achieving the report's goal of "Adoption of Universal Exchange Language to Mobilize Data, Improve Healthcare, Enhance Privacy, and Cut Costs" be the subject of further study and a separate report.

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1 See letter from Initiative for Software Choice at www.softwarechoice.org/download_files/HHSBrailler0705.pdf (last access 1/30/11).

2 On September 15, 2008, H. 6898 was introduced before the 110th Congress, and called for the establishment of a federal open source Health IT system. Sec 3001(c)(4) of that Act reads as follows:

(4) FEDERAL OPEN SOURCE HEALTH IT SYSTEM-
(A) IN GENERAL- The National Coordinator shall provide for coordinating the development, routine updating, and provision of an open source health information technology system that is either new or based on an open source health information technology system, such as VistA, that is in existence as of the date of the enactment of this title and that is in compliance with all applicable standards (for each category described in paragraph (2)(A)) that are adopted under this subtitle. The National Coordinator shall make such system publicly available for use, after appropriate pilot testing, as soon as practicable but not later than 9 months after the date of the adoption by the Secretary of the initial set of standards and guidance under section 3003(c).
(B) CONSORTIUM- In order to carry out subparagraph (A), the National Coordinator shall establish, not later than 6 months after the date of the enactment of this section, a consortium comprised of individuals with technical, clinical, and legal expertise open source health information technology. The Secretary, through agencies with the Department, shall provide assistance to the consortium in conducting its activities under this paragraph.
(C) AUTHORIZATION TO CHARGE NOMINAL FEE- The National Coordinator may impose a
nominal fee for the adoption by a health care provider of the health
information technology system developed or approved
under subparagraph (A). Such fee shall take into account the
circumstances of smaller providers and providers located in
rural or other medically underserved areas.
(D) OPEN SOURCE DEFINED- In this paragraph, the term 'open source' has the meaning given
such term by the Open Source Initiative.[www.opensource.org]

(See http://thomas.loc.gov for full text of H. 6898 (last access 1/30/11).

3 /Evaluating Open Source Software for Health Information Exchange,/ published by the Health Information Management
Systems Society (HIMSS) in June of 2008 contains the following
statement: "A recent study demonstrated that a
substantial number of projects in the U.S. Department of Defense and in
the Intelligence communities have been
implemented using open source software and that security considerations
were critical in making the choice. If anything,
use of open source software enhances security." The full text is
available at
www.himss.org/HIMSSWeeklyInsider/HIMSSWeeklyInsider_20080827.htm (last
access 1/30/11).

4 Herbsleb, James, /The VistA Ecosystem: Current Status and Future
Directions/ http://conway.isri.cmu.edu, as well as

*       *

I would be most grateful for the courtesy of a reply. I have made some
of the ideas contained in these comments known in written communications
to the President and to Secretary Sebelius in the past, without so much
as an acknowledgment, let alone a substantive reply.

--
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Pittsburgh, PA  15219-1826
Tel 412 683-6015  1-866-594-6015 (Toll Free)
Fax 412 683-6430

Changing health systems for the 21st Century

Attachments:
untitled-[2]
Size: 7.8 k
Type: text/html
Education & Economic Sustainability
Jumping hurdles & overcoming obstacles

27 Jan 2011, Thursday
Tim Williamson
Brookwood, Alabama, USA

Why are we not teaching exclusively the metric system when we know its importance in the development of new technologies and new industries, and in all the sciences and in global trade? Is it because we want our children to jump over the same hurdles and overcome the same obstacles we confronted in our youth, even though it is not productive or necessary? Or, maybe we are hanging on to a piece of our nostalgic past hoping that if we keep doing the same thing over and over again, we’ll get a different and better result.

Sorry! Those days are gone.

Why do we continue to jeopardize future jobs, and our economy, by asking our children to overcome a series of self-imposed obstacles and hurdles just to compete on the same field as the rest of the world in sciences and math? Do we not know that the sciences and math are the foundations of all innovation in the new technologies which will be the cornerstone of our economy, of new industries, and therefore of jobs?

For the most part, everyone knows that long-term economic sustainability is directly tied to educational excellence. Tomorrows jobs will primarily be high tech jobs, and the success of the US is dependent upon consistent, uniform and challenging educational standards and dedicated R&D programs in the sciences. We know that the old industries have left and will not return and that new industries based on new technologies will be the backbone of tomorrows economy.

New technologies do not develop in a vacuum, nor do they appear out of thin air in some miraculous way. Technological innovations arise from excellence, creativity and innovation in the sciences and math - from knowledge - not from a course in underwater basket weaving. Educational excellence in the sciences and math is therefore the principle basis of any real sustainable economic policy for our country, or any country for that matter.

Those countries that pursue educational excellence in the sciences and math and reading skills will be tomorrows economic leaders. It is that simple. Unless the US makes a concerted effort to remove all obstacles and eliminate all hurdles to success, creativity and innovation in the sciences and math throughout our schools and businesses, we will become a third world ‘has been’ who thought they could rest on their laurels and the world would go our way. We either make the necessary changes now, or we will surely fail together in our stubbornness and obstinacy.

What are some of the obvious obstacles our children and grandchildren must
overcome to compete in the global marketplace of ideas and new technology? One obstacle is the lack of widespread and mandatory use of the metric system throughout our educational systems and businesses. The metric system is used exclusively in the sciences, but most do not know that it is already used in all science based industries today in the US. The metric system is also the language of trade, so why are we not making the metric system the exclusive measurement system of the US when it is a foundational language of science and trade throughout the world? Why not get all our schools to use and teach the metric system without dual measurements being discussed? Teaching dual units of measure and the conversions between them is simply an attempt at procrastination, and adds to the confusion our students confront daily. Why add to the challenge. Just teach only the metric system.

Tim Williamson
1-205-765-6090

Attachments:
untitled-[2]
Size: 9.5 k
Type: text/html

From: "Nicola Jones" <nkjones@gmail.com>
Subject: Invitation from the science journal Nature
Date: Thu, January 20, 2011 8:00 pm
To: rwweiss@ostp.eop.gov,The.Secretary@hq.doe.gov,pcast@ostp.gov,ostpinfo@ostp.eop.gov,mjmolina@ucsd.edu,zewail@caltech.edu,Carl_E._Wieman@ostp.eop.gov
Cc: jholdren@ostp.eop.gov

Dear all,

Nature has recently been made aware (thanks to John Holdren's speech at the AGU) that there are currently a record 5 science-Nobel-Prize-winners working for the US President in various roles. Nature would like to commemorate this event by conducting a short survey of these scientists, with the intent of publishing the replies (edited for length) in Nature's comment section.

I have some direct email addresses, and some press contacts, to help reach the five: Carl Wieman, Steven Chu, Harold Varmus, Mario Molina, and Ahmed Zewail.
If you can help to direct this email to the attention of these scientists, I would greatly appreciate it.

We are hoping for short replies (no more than 300 words each) to the following questions, sometime in the next few weeks:
1) What one thing would you like to achieve during your government post?

2) What was your worst/best day in this post so far? How do the rewards and frustrations of policy work or diplomacy compare to those of research?

3) What one-sentence piece of advice would you give a researcher hoping to make a difference to policy?

4) What do you think is the best example of how scientific advice or information has changed or improved a US policy decision (from your own work, or that of others)?

If you could please confirm receipt of this note, and provide an estimated time of reply, it would be greatly appreciated.

Best wishes,
Nicola Jones.

--

Ms. Nicola Jones
Science Journalist in Residence, UBC School of Journalism
Commissioning Editor, Opinion section, Nature (Tues / Wed / Thurs, 8am-5pm PST)
Freelance Reporter, Vancouver (Mon-Fri, 8am-5pm PST)
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Attachments:
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Size: 2.4 k
Type: text/html

From: "Robert Halford" <robertjhalford@gmail.com>
Subject: A response to PCAST regarding "Designing a Digital Future"
Date: Thu, January 13, 2011 12:14 pm
To: pcast@ostp.gov
Cc: "Qualters, Irene M." <iqualter@nsf.gov>

Dear PCAST Team,

The attached 9-page .pdf document is a response to your presidential briefing on "designing a digital future". I've been wrapped up in that process for the past decade myself; however self-inflicted. I enjoyed reading through it and decided to reply immediately. I certainly agree with
your findings and predictions. I also believe that I might have some solution to a few of your outstanding concerns.

Perhaps not all of your team will be interested in my response but I would certainly like to see those with specific interest in the area of data reliability and data integrity have a read. My goal is to find help in ways of getting this technology developed, integrated into systems and into the hands of users of critical data. Dollars are important too; we've bet the farm on this project and are currently running on empty. I'm sure that you appreciate the difficulty in getting change accomplished both within and outside established companies.

I have disclosed this technology to many companies via NDA prior to receiving the patent and to many more without a DA since. What is disclosed within the document has been published in the patent applications or elsewhere.

Sincerely;

Robert J. Halford
Micro_Mirroring Technology
18703 67th Ave. Chippewa Falls, WI 54729

715 - 723 - 7782

cc
Irene Qualters, NSF

Attachments:
- **untitled-[1.2]**
  - Size: 1.6 k
  - Type: text/html
- **Micro_Mirroring.pdf**
  - Size: 2.1 M
  - Type: application/pdf
A proposal to the President’s Council of Advisors on Science and Technology

Micro_Mirroring, a revolutionary data protection solution

Robert J. Halford, Micro_Mirroring Technology

All Way End-to-End Data Protection Interconnect for Healthcare Data Records
I have read ‘Designing a Digital Future: Federally Funded Research and Development in Networking and Information Technology’ and agree with your findings and the challenges faced by 21st century technologists designing fail-safe systems and critical data applications.

I’m an electrical engineer with experience at companies including Cray Research and Silicon Graphics. Most of my work has been in the architecture, design and development of HPC storage systems including I/O systems, HDDs, SSDs, HPC system channels and error control coding. At Cray Research I was Chief Engineer for I/O and was granted several patents in the fields of systems and storage.

In recent years I have been working independently on some of the very issues that you illuminate in your briefing. I call my resultant work and proposed solution Micro_Mirroring Technology and present it as “A solution for tomorrow’s physical storage resiliency and data integrity requirements”. The technology is based on intellectual property primarily supported by U.S. Patent No. 7,103,824 titled Multi-dimensional data protection and mirroring method for micro level data.

A number of well designed studies have been completed and papers written presenting large scale analysis of errors within contemporary processing and storage systems. Google, CERN, Carnegie Mellon University, University of Wisconsin, NetApp Inc., University of Toronto and the University of Illinois have led many of these efforts. They report that error rates tend to run higher than specified by vendors of Hard Disk Drives, Flash memory, DRAM memory and small dimension circuitry. Also quite often there are gaps in the protection systems that allow errors to propagate.

Data availability, data reliability, data integrity, data resiliency, data consistency and data security are all critical areas of design for these new important data applications. The same commodity microprocessor, network and storage technology I’m using to write this proposal will also be used by a doctor to evaluate healthcare records, make medical decisions then write procedures, prescriptions and edit the existing records. For the case where a doctor is using a hand-held tablet pc coupled to a data-base on a cloud server the amount of hardware and software components involved can be extensive. And data integrity and reliability protection isn’t up to the standards expected or desired for such critical information. But this has already become the new norm with the tsunami of mobile devices and applications. It may be imperative that applications involved with critical information incorporate data protection techniques in order to achieve a valid end-to-end data integrity coverage.

Micro_Mirroring incorporates modern algebraic concepts to better protect, detect, correct and recover data corrupted by any of hundreds of failure modes within lengthy networks, high-speed digital circuits and high density storage devices. Micro_Mirroring is designed to complement but not replace other new solutions such as those that manage the storage consistency issues, data compression and de-dup, or standards for cloud based object data. I note your reference to Google’s Big Table design. So, there is no need to throw any good little babies out with the bathwater.
I would like to further convey what I propose is a necessary shift in the way critical data such as object based healthcare records are protected. Micro_Mirroring addresses these issues in the following priority.

1. **Immediate encoding is mandatory for a statistically reliable write or data capture and becomes the very foundation for data integrity.**

   Encoding should occur the instant data is “sensed” or “computed” and before it is moved elsewhere within the system. The physical integrity of even the first circuit paths or storage media invoked must be assumed less than perfect. With critical systems that are very large and very fast even small error rates will statistically come into play. In the case for medical records this requirement must be addressed at all nodes including image or DNA sensors, record storage and even mobile devices entering or modifying digital record information. Presently when data is corrupted it is difficult to point a finger at what was responsible. The requirement for a reasonable level of data integrity quality will soon become akin to food quality or vehicle safety quality. Instances of poorly protected data could get litigated when determined to be responsible for losses. Micro_Mirroring is designed specifically to replace existing less effective yet more complex solutions.

2. **Unlike conventional data protection approaches Micro_Mirroring provides each data object an integrated data protection capability.**

   In a nutshell Micro_Mirroring differs from conventional mirroring by making an algebraic copy of each data byte in place of an exact binary copy. The algebraic copy can physically accompany the binary data byte or be dispersed as with conventional binary mirrors. Thus Micro_Mirroring can operate either in-band or out of band. The Hamming distance of each two-byte codeword is maximized for error detection and correction purposes. This and other attributes make this small change a disruptive game changer for data reliability and resiliency. Most advantageously, this capability lends itself to the emerging format of objects vs. records and files.

   Simple guidelines permit software to apply this technology when and where necessary. Micro_Mirrored data can be encoded, decoded or verified at any location within a system and at any time. The advent of multiple cores and embedded cores may favor a software implementation for most applications. However since both the encoding and decoding processes are single step XOR functions they can be done very efficiently in the simplest of logic circuits to attain any desired bandwidth.

3. **Micro_Mirroring, like raid-1 and raid-10 is 50 per cent efficient but provides full resiliency to dual failures. When considered in groups of eight units it provides a high probability of recovery for three and even four simultaneous failures.**

   Certainly single failure resiliency is normally required and dual or triple recoveries are often specified. Conventional mirroring via RAID-1 methods provides single failure resiliency and RAID-10 provides but a partial capability for dual failures.
A proposal to the President’s Council of Advisors on Science and Technology
January 11, 2011

4. Micro_Mirroring provides such a powerful data validation capability that it can be advertised as a “data certification receipt” for each object verified. It also provides an optional “byte-by-byte log of data integrity” when errors are determined.

A really complete end-to-end data validation has long been desired. Over the past decade the SNIA & ANSI standards bodies have attempted to meet this requirement. While making an improvement it is but a partial ‘band-aid” solution with very limited error detection and no error correction capability thus leaving much to be desired.

For data validation purposes Micro_Mirroring checks each 8-bit data byte against its very powerful 8-bit CRC / ECC byte. Each linear data byte can self-detect and self-correct two random bits in error. For a bit error rate of $10^{-12}$ the probability for an undetected error for conventional mirroring is $8 \times 10^{-24}$ and the same probability for Micro-Mirroring is $2.4 \times 10^{-59}$. These calculations are for a single data byte.

The combination of the linear byte validations along with a HASH signature result in a very robust and high-fidelity data certification method. The summary of all errors and corrections provide for a fine-grained error isolation report.

5. Micro_Mirroring amplifies the current Hash signature’s ability to protect against the most common trick used to disguise maliciously altered data.

An attribute of Micro_Mirroring arises when both the original data object and the algebraic data object provide unique Hash signatures. Now any monkey-ing with the original data object in multiple places in order to hide an altered digit or so becomes much more difficult. And when data is dispersed four ways four additional HASH signatures become available. This makes it possible to consider a total of six HASH signatures when validating each data object.

6. Micro_Mirroring improves upon the commonly used ARQ algorithm to make high-speed system channels resilient to line failures and become more autonomic.

Persistent single-bit line failures are a common fault within system channels. Conventional channels such as AMD’s HyperTransport interface utilize an age-old recovery algorithm called ARQ, Automatic Retry Request. If a data transport packet is received correctly an acknowledge, ACK, signal is returned to the transmitter logic and the next data packet is transmitted. If the data packet is determined to be in error a negative acknowledge, NACK, signal is returned and the original packet is retransmitted. A persistent error or failed bit path results in an endless retry loop or the necessity to down the path and if possible reroute the data.

With Micro_Mirroring it is possible to send the algebraic copy of the data packet upon reception of the NACK signal allowing the receiver to recover the original data and also identify and log the exact bit path locations of the fault.
Summary of Micro_Mirroring’s advantages and attributes:

- Micro_Mirroring specifies an immediate data encoding for replication and multi-channel dispersal for a true end-to-end protection of data objects.
- Micro_Mirroring provides each data object with its own unique integrated data protection mechanism with the ability to self-detect and correct two random bits per data byte.
- Micro_Mirroring provides resiliency to multiple simultaneous catastrophic hardware or data failures and many other error modes.
- Micro_Mirroring provides a very robust high-fidelity data validation, correction and certification capability plus an optional data integrity log with byte level granularity.
- Micro_Mirroring obsoletes simple binary mirroring for data resiliency by making data many orders of magnitude less prone to random bit error corruption.
- Micro_Mirroring makes data objects more secure by amplification of HASH signature checks.
- Micro_Mirroring has the capability to make systems and channels more autonomic.
- Micro_Mirroring is efficiently encoded and decoded via either software or hardware methods.
- Micro_Mirroring is well suited for protecting ultra long DNA data objects.
- Micro_Mirroring has the flexibility to address future systems’ error modes.
- Micro_Mirroring should lower the total life cycle cost of servers and storage by eliminating or simplifying many point products and associated software maintenance.
- Micro_Mirroring should greatly improve on error and failure isolation for ease of system maintenance.
- Micro_Mirroring can protect and validate your digital healthcare records even when they are on a USB memory stick(s) in your pocket or purse or embedded on your person.
- Micro_Mirroring provides both vendors and users of all types of critical records a unique new “industrial strength” comfort level in data safety and quality assurance.
A final consideration: Micro_Mirroring replication is very similar to DNA replication

- Both replicate with a non-identical pairing (unlike conventional binary mirroring) for reasons that are now obvious. It self-protects!
- Both share the ability to split apart and replicate individually and simultaneously for performance and efficiency!
- Both can be any length as per the definition of data objects. There is no artificial record size!
- Both share the ability to perform error detection and correction (unlike conventional binary mirroring).
- Both allow segments of data to be inserted, deleted or modified as long as the opposite “strand” is likewise changed.
- Micro_Mirroring has a 256-character alphabet based on 8-bit data bytes meeting today’s computing requirements.

DNA has a 4 character alphabet; meeting biological and chemical requirements (Credit Madeleine Price Ball for the DNA diagram).

**DNA Replication**

Consider one spiral of helix to be DATA and the other to be ECC

A – T
C – G
G – C
T – A
Micro_Mirroring uses a 256-character alphabet. Note the software look-up table.

This table of codewords are based on row values generated using the example ECC polynomial \( g(x) = 1 + x^3 + x^4 + x^5 + x^8 \). The table can be expanded to provide look-up data for single and dual failure recoveries.

The codeword \([\text{DATA}_i]\) \([\text{ECC}_i]\) = \(d^6d^4d^2d^3d^5d^6d^7e^6e^4e^2e^3e^5e^6e^7\)

The codeword in binary array form:
\[
\begin{align*}
[\text{DATA}_i] & \quad d^6d^4d^2d^3 \text{ s } \{\text{hexadecimal row dispersal}\} \\
& \quad d^6d^4d^2d^3 \text{ t } \\
[\text{ECC}_i] & \quad e^6e^4e^2e^3 \text{ u } \\
& \quad e^4e^5e^6e^7 \text{ v } \\
\end{align*}
\]

\[w \times y \times z \] \{\text{hexadecimal column dispersal}\}

### Micro_Mirroring™ table of codewords for row dispersion

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<th>Da</th>
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All Way End-to-End Data Protection Interconnect for Healthcare Data Records

Please contact Micro_Mirroring Technology regarding a more detailed presentation or if interested in licensing or purchasing the IP. We are also looking at a potential development project.

Micro_Mirroring Technology appreciates your assistance too. Thanks,

Robert J. Halford
Micro_Mirroring Technology
18703 67th Ave. Chippewa Falls, WI 54729

robertjhalford@gmail.com
robert.halford@miner.mst.edu

715.723.7782
715.944.9181 cell
Good Afternoon,

Attached are written comments from Dr. Barbara Glenn, VP, Science & Regulatory Affairs, CropLife America.

If you have any questions, or need anything else, please do not hesitate to contact me.

Best Regards,

Stephanie R. Lutz
Science & Regulatory Affairs Assistant
CropLife America
1156 15th St., NW, Ste. 400
Washington, D.C. 20005
Phone: (202) 872-3867
Fax: (202) 463-0474
Email: StephanieLutz@croplifeamerica.org
<mailto:StephanieLutz@croplifeamerica.org>

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January 7, 2011

Submitted to Federal e-rulemaking Portal

Distinguished Co-Chairs of President’s Council of Advisors on Science and Technology:
Dr. John P. Holdren
Assistant to the President for Science and Technology, and
Director, Office of Science and Technology Policy

Dr. Eric S. Lander
President and Director, Broad Institute of MIT and Harvard

Office of Science and Technology Policy
Executive Office of the President
725 17th Street Room 5228
Washington, DC 20502

Re: Office of Science and Technology Policy, President’s Council of Advisors on Science and Technology; Notice of Meeting: Partially Closed Meeting of the President’s Council of Advisors on Science and Technology [Docket No. 2010–31229] 75 FR 77679. December 13, 2010.

Dear Drs. Holdren and Lander:

CropLife America (CLA) is pleased to provide comments to the Office of Science and Technology Policy’s President’s Council of Advisors on Science and Technology on the occasion of the meeting held on January 7, 2011 in which the Council is addressing agriculture research and development. We laud PCAST’s objective to make policy recommendations in the many areas where understanding of science, technology, and innovation is key to strengthening our economy and forming policy that works for the American people.

CLA is the non-profit trade organization representing the nation’s developers, manufacturers, formulators and distributors of plant science solutions for agriculture and pest management in the U.S. Our member companies produce, sell and distribute virtually all the crop protection technology products used by American farmers. CLA comments on issues that can have broad science and regulatory implications that may impact growers and our members. CLA and its predecessor organizations recently celebrated a 75th anniversary.
The current status of food and agricultural research structure, organization and priority setting has advanced this past year, but in spite of the compelling nexus of benefits, needs and priorities, funding remains nearly static.

- The benefits from agricultural research continue to be a foundation for societal well being and growth.
  - For example, the benefits from crop protection are vast. Large scale commercial production of fruits and vegetables has been achieved only with judicious use of insecticides and fungicides. Without the use of these products, more than 50% of crops were lost. Today, with the standards of the American consumer, it is likely that without the use of these products, more than 50% of fruit and vegetable products would be unacceptable. Over the past 50 to 60 years, herbicide use has significantly increased crop yields, substituting for millions of additional acres that would otherwise be required, and allowed for reduced tillage, reducing soil erosion by billions of pounds, which is a cornerstone of sustainable agriculture. Similar science success stories abound in the agriculture sector.

- The grand challenges remain the same: global food security and safety, human health, hunger, and sustainability.

- Food and agricultural research continues to pay off with nearly a 50 percent average social rate of return to public investment (U.S. Department of Agriculture (USDA) Economic Research Service (ERS) September 2007 Economic Brief titled, "Economic Returns of Public Agricultural Research").

- In spite of the compelling nexus of benefits, needs and priorities, funding for food and agricultural research remains nearly static. Recent vigorous efforts to increase research funding by the Administration, the USDA and most organizations involved in agriculture and food production were thwarted and ag research remains dramatically under funded, reflecting the socio-economic and political landscape.

CLA believes that federal funding for food and agricultural research, extension and education represents a top national priority and a necessary long-term national commitment. As a member of the National Coalition for Food and Agricultural Research (N CFAR) CLA believes that strong, consistent public funding for food and agricultural research conducted through programs of the USDA is critical to the continued discovery of new modern agriculture solutions. The investment is critical to training students who will be the future experts in food and agricultural sciences in both the public and private sectors. **We support USDA’s leadership in research, extension and economics mission area, but the funding limitation severely impacts their ability to adequately address the grand challenges.**

The crop protection industry conducts significant research based on a rigorous science-based regulatory process. Indeed, it has been summarized that the cost of research and development for one pesticide to reach commercialization is now ten years and $256 million (CLA and European Crop Protection Association, 2010. The Cost of New Agrochemical Product Discovery, Development and Registration in 1995, 2000 and
2005-2008. R&D Expenditure in 2007 and expectations for 2010. Final Report, January 2010. We support the need for public funding for research, as a necessary complement to private sector research. We endorse coordination of research in public-private partnerships which will assure that research is prioritized and relevant to American farmers and the environment.

There is no doubt that food and agricultural research will continue to pay off. We cannot take modern agriculture or the research that supports it for granted. Scientific research forms the cornerstone of modern agriculture including safe crop protection products that have been registered through a rigorous, science-based regulatory process. We must invest in crop protection research, innovative farming methods and new technologies to meet the unique challenges faced by agriculture and consumers worldwide who rely on it. In the future, new pesticides of reduced risk will be registered and used in enhanced integrated pest management approaches for all crops. Seed and fertilizer will be improved. Application technologies will continue to improve growers’ abilities to integrate all of the crop inputs, using global positioning systems and geospatial information systems, while producing safe and healthy food and reducing the environmental footprint.

The benefits, pay offs and challenges are too great to ignore. Notwithstanding the current economic and political landscape, CLA urges PCAST to recommend increasing public investment in U.S. food and agricultural research to ensure both U.S. and international food security. Provide the Administration with creative solutions and pathways to build that public investment. The crop protection industry is committed to helping you as we help farmers produce an affordable and sustainable supply of food to help feed a hungry world - the benefits and new opportunities offered by modern agriculture.

We appreciate the opportunity to comment. If there are questions, please do not hesitate to contact me (202- 833- 4474; bglenn@croplifeamerica.org).

Sincerely,

Barbara P. Glenn, Ph.D.
Vice President
Science and Regulatory Affairs
Dear Sir/Madam:

Attached please find comments from the American Veterinary Medical Association related to the January 7, 2011 PCAST meeting. Should you have any questions, please contact Dr. Beth Sabin, Assistant Director in the AVMA's Education and Research Division (esabin@avma.org; 800-248-2862, ext 6675).

Thank you for the opportunity to provide comments to PCAST.

Sincerely,

Eileen Hoblit

******************************************************************************

Eileen Hoblit

Administrative Assistant, Education and Research

American Veterinary Medical Association

1931 N. Meacham Rd., Suite 100

Schaumburg, IL 60173-4360

Phone: 847-925-8070 or 800-248-2862, ext 6778

Fax: 847-285-5732

E-mail: ehoblit@avma.org

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January 7, 2011

President’s Council of Advisors on Science and Technology
Office of Science and Technology Policy
Executive Office of the President
725 17th Street Room 5228
Washington, DC 20502
pcast@ostp.gov

Dear Co-Chairs Holdren and Lander and Members of PCAST:

I am writing on behalf of the American Veterinary Medical Association (AVMA), established in 1863 and the largest veterinary medical association in the world. As a not-for-profit association established to advance the science and art of veterinary medicine, the AVMA is the recognized national voice for the veterinary profession. The Association’s more than 81,000 members comprise approximately 83% of US veterinarians, all of whom are involved in myriad areas of the profession, including biomedical and comparative medical research; agricultural research; private and corporate practice; and academic, industrial, governmental, military, and public health services.

The AVMA thanks the President’s Council of Advisors on Science and Technology (PCAST) for this opportunity to provide written comments to expand on oral comments presented by Dr. Michael Newman, Member of the AVMA Council on Research, during your January 7, 2011 meeting. The AVMA firmly believes that continued and increased federal funding is essential to maintain and develop strong research programs for the advancement of the agricultural, biomedical, and veterinary sciences. The veterinary medical profession has the national responsibility to care for and protect animal health, public health, food systems, and environmental and ecosystem health. However, veterinary stewardship in these areas is challenged by new and re-emerging diseases that arise from characteristics particular to today’s society, including globalization of commerce; commercialization and consolidation of food supplies; increasing transportation efficiencies; greater encroachments at animal-human-environmental interfaces; and the threat of bioterrorism. As such, innovative strategies developed through current research efforts will be required to successfully and effectively address such diverse risks into the future.

Although strong research programs to advance agricultural, biomedical, and veterinary sciences are essential to ensure the health and well being of the US public and its animals, the AVMA notes that levels of federal funding for basic, clinical, and applied animal health research have declined significantly over the past decade. We believe this may underscore the under-recognized of the role that such research has in providing an adequate and safe food supply for our nation and that of the world. It also affects our nation’s ability to develop disease-resistant food animals, vaccines, and other interventions to protect our national food animal herds and flocks against devastating animal diseases, as well as impacting the development of new and effective approaches to disease surveillance, diagnostics for early disease detection, and effective population-based therapies.
The AVMA applauds the current Administration and federal agencies such as the USDA’s National Institute of Food and Agriculture (NIFA) for reaffirming their commitment to science, research, education, and extension. We note that many of the AVMA’s research priorities and imperatives complement the issues identified by the USDA as priority science areas—Global Food Security and Hunger, Food Safety, Sustainable Energy, Childhood Obesity, and Climate Change (see, for example www.avma.org/issues/policy/research_priorities.asp). In addition, the AVMA strongly supports and affirms the recognition by the NIH of the role of veterinarians as scientists, educators, trainers, and collaborating partners in scientific research that takes a comparative, one-medicine approach to improvements in human and public health, as stated in the recent National Center for Research Resources (NCRR) 2009-2013 strategic plan (available at www.ncrr.nih.gov стратегических планов/). Because contributions by veterinary basic scientists and clinical researchers will be critical for energizing the discipline of clinical and translational research across the country, the AVMA urges the continuation of federal funding to support and expand opportunities for veterinary scientists and veterinary students to engage and participate in scientific education and training, research teams, and science policy and leadership roles, through the expansion of formalized training positions, broadening of debt-forgiveness clauses, and appointment on relevant federal agency committees and councils.

The AVMA also believes that the animal health and agricultural research community must begin to move away from single pathogen/single disease approaches to more comprehensive diagnostic, vaccine, and therapeutic platforms that address multiple animal diseases. As such, the AVMA believes that focus areas for future federal funding must include:

- Application of functional genomics, transcriptomics, and proteomics systems biology and analyses of infectious, parasitic, and metabolic diseases of livestock species to develop predictive biology approaches for discovery of the next generation of diagnostics, vaccines, and pharmaceuticals.
- Technological and personnel approaches to improve food safety and science-based risk analysis.
- Development of multipathogen and multimodality multiplex handheld diagnostics for major livestock species, including systems to detect emerging infectious and parasitic pathogens and antimicrobial resistance.
- Increasing the understanding of potential impacts of climate change on animals and ecosystem health.
- Development of a scientific knowledge base regarding judicious therapeutic antimicrobial use, to include enhanced risk analyses processes to determine actual risks of antimicrobial resistance from their use in animal agriculture.

The AVMA appreciates this opportunity to provide input to PCAST as it continues its important work in advising the President of the United States in areas where an in-depth understanding of science, technology, and innovation is key for the development of strong policies to strengthen the American economy and protect the American people. We believe that continued and strong federal investment in agricultural, biomedical, and veterinary research will serve to do just that.

Should you have questions, please feel free to contact Dr. Elizabeth Sabin (esabin@avma.org; ext 6675), Assistant Director in the AVMA’s Education and Research Division.

Yours sincerely,

Elizabeth A. Curry-Galvin, DVM
Assistant Executive Vice President
CAST (The Council for Agricultural Science and Technology) submits the following research area suggestions.

1. Enabling C3 plants to utilize C4 photosynthetic pathways
2. Introducing nitrogen fixation in nonlegumes
3. Incorporating the process of apomixes into crop plants
4. Enhancing water and nutrient efficiency of crop species
5. Developing processes for more efficient conversion of cellulose, hemicelluloses and lignocelluloses to fuel
6. Improving pest resistance in plants
7. Improving energy efficiency in plants
8. Developing commodities with increased health benefits
9. Developing processes to capture photosynthetic processes in the oceans
10. Develop effective and efficient processes for capturing and utilizing all animal waste
11. Eliminate all respiratory disease in livestock
12. Utilize the power of genomics and biotechnology to improve food animals
Dear Members of the President's Council of Advisors on Science & Technology:

Please find attached a statement in support of USDA-NIFA competitive grant programs, specifically the Specialty Crops Research Initiative program, for the PCAST meeting on Friday 7th January, 2011.

Sincerely,

John Lea-Cox

Dr. John Lea-Cox
Associate Professor, Nursery Research and Extension Specialist
Department of Plant Science and Landscape Architecture,
2120 Plant Sciences Building
University of Maryland
College Park MD 20742-4452

Tel: (301) 405-4323 (Office)
Fax: (301) 314-9308

[http://www.smart-farms.net/]

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Statement in Support of the USDA-NIFA Specialty Crop Research Initiative (SCRI) Grant Program

Over 79% of the world’s fresh water is used for agriculture. The US faces major challenges with surface water supply (e.g. California), groundwater depletion in the Ogallala Aquifer, supplying water to our breadbasket states (Kansas, Oklahoma, Nebraska), and droughts. Climate change will amplify these issues in the future.

With the correct information, horticultural producers can reduce both their water use and runoff without compromising plant quality. The SCRI–MINDS project (Managing Irrigation and Nutrients with Distributed Sensing) is a 5-year project funded by USDA-NIFA and brings together scientists, engineers and economists from five universities (Maryland, Carnegie Mellon, Georgia, Colorado State and Cornell) and two companies (Decagon Devices and Antir Software), to develop and deploy smart sensor networks for specialty crop growers, and provide producers with real-time information to make better irrigation decisions every day.

One of the notable features of this research program is that it requires a dollar-for-dollar match from non-federal sources. Nearly $1M of the $5.2M in non-federal matching dollars is coming from the nine commercial nursery and greenhouse growers involved in the project; another $1M is coming from the two commercial companies – contributions in time, equipment, expertise and advice, which will help us deliver a product that will keep horticultural producers amongst the most productive and efficient in the world.

Three important points about the focus of this grant:
1. The greenhouse and nursery industry consists largely of small family-owned companies across the United States, which are unable to support this type of research by themselves, so federal funding is critical.
2. Nursery and greenhouse agricultural systems are very complicated production environments; these industries are a microcosm for specialty crops in general, which provide over half of US farm-gate income.
3. Findings from this work most likely extend into areas outside of traditional nurseries and greenhouses.

We are also replicating this work in non-traditional horticultural applications, such as green roof models, to test the breadth of applications.

After just one year, this project is already delivering these important impacts:
- Water management in horticultural crops is very intensive and greatly affects crop quality; accurate information can help growers better manage expensive inputs and reduce labor costs.
- By reducing irrigation water applications to crops, growers not only increase the efficiency of water use, but reduce fertilizer leaching, improve plant quality, and reduce disease pressure on crops. Our scientific teams have made some early progress in documenting this information for producers.
- Existing sensor technology has been deployed in the commercial operations and we have already reduced water applications by up to 50%, by using information from simple soil-moisture sensor networks.
- Carnegie Mellon and Decagon Devices are developing next-generation sensor network hardware that are capable of making independent irrigation decisions in the field, based on information from a whole suite of environmental sensors (like temperature, relative humidity and daily sunlight accumulation)
- Understanding the implications made of decisions made from sensor data is a key deliverable of this project, driven by the knowledge gained from our scientific teams. The challenge is to translate this knowledge from the sensor networks to growers using an intuitive graphical software program.
- We are also developing advanced software that will integrate the information from these sensor networks with plant growth models. This will provide growers with predictive water use information about their crops, increasing their management expertise and production efficiency.
- Our economic teams are documenting not only the on-farm economic benefits of this technology with our growers, but also documenting the larger social and economic benefits for society.
- Society benefits from this research because it will reduce the environmental impact of greenhouse and nurseries by reducing the amount of water use that is used, and by decreasing leaching and runoff of fertilizers, pesticides and fungicides from production sites.

The project incorporates multidisciplinary research by over ten science and engineering graduate students and research associates; faculty continuously integrate information into undergraduate and graduate courses. An online knowledge center will also provide up-to-date resources and information for growers and the general public with in-depth learning modules.

For more details about the project, please visit http://www.smart-farms.net or contact the principle investigator, Dr. John Lea-Cox at jlc@umd.edu
I tried posting on these comments website, but evidently not scientific to sort it out!

My oral comments of course will be considerably more concise and within the prescribed 2 minute time period!

Tom

R. Thomas (Tom) Van Arsdall, National C-FAR Executive Director

Van Arsdall & Associates Inc.

(703) 509-4746

mailto:tom@vanarsdall.com

National Coalition for Food and Agricultural Research
<http://www.ncfar.org/>
The National Coalition for Food and Agricultural Research (National C-FAR) appreciates this opportunity to share our views with the President’s Council of Advisors on Science and Technology (PCAST). PCAST has the important charge of providing expert recommendations to the President in the many areas where understanding of science, technology, and innovation is key to strengthening our economy and forming policies that work for the American people. Toward that end, National C-FAR urges PCAST to support necessary increases in funding for food and agricultural research, extension and education (RE&E), and to help craft innovative funding approaches.

National C-FAR recommends and supports—
- Increasing funding in ALL parts of USDA’s RE&E mission, both intramural and extramural.
- Funding the National Institute of Food and Agriculture’s (NIFA) Agriculture and Food Research Initiative (AFRI) at the fully authorized level as soon as practicable, without taking funds away from other RE&E programs.
- Increasing funding for the remainder of NIFA beyond AFRI—including the Agricultural Research Service (ARS), Economic Research Service (ERS) and Forest Service (FS).
- Continuing to leverage USDA funds in partnerships with other federal agencies that advance ag science.

By any measure, this is a wise and necessary investment, with fundamental benefits to society. According to a USDA, Economic Research Service report, the median annual rate of return for public investment in agricultural research is 45 percent, returning $10 in economic benefits for every taxpayer $ invested.

You will be benefiting from presentations this afternoon by USDA Under Secretary and Chief Scientist Cathie Woteki and NIFA Director Roger Beachy about innovative reforms being undertaken to maximize the effectiveness of USDA’s research mission in an effort to produce the science needed to achieve critical national objectives. Research is needed to achieve multiple societal needs and demands that matter. Science-based outcomes can lead to through increased productivity, optimized utilization efficiency, improved nutrition and food safety, sustainable natural resources, protection of our environment, developing the next generation of biofuels and other benefits that benefit our Nation.

National C-FAR supports their leadership efforts and urges your close attention to the good information and recommendations we anticipate they will present. Advances in ag science are important to our nation’s future. Yet the best concepts about how to organize and conduct research won’t be able to deliver the vital results needed by our Nation unless sufficient funding is provided. The reality is that their work is hamstrung by a longstanding, chronic shortage of funds. Federal funding for food and ag research has been essentially flat for over 2 decades, and has declined by about ¼ in real terms since FY03. Growing societal demands and expectations placed upon the food and ag system are far outstripping our nation’s ability to develop the science and tools to respond.

The need is clearly demonstrated. NOW is the time to act—to grow investment in our nation’s agricultural scientific research enterprise to a sustainable level. If you agree, please add PCAST’s considerable stature in support of increased funding. Innovation is critical to science. In the current budget climate, so too is innovation critical. National C-FAR urges PCAST to help this Administration develop innovative approaches to provide the necessary funding for food and ag RE&E.

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1 National C-FAR is a nonprofit, nonpartisan, consensus-based and customer-led coalition that brings food, agriculture, nutrition, conservation and natural resource organizations together with the food and agriculture research and extension community in unified support of sustaining and increasing public investment at the national level in food and agricultural research, extension and education. More information is available at http://www.ncfar.org or by contacting Executive Tom Van Arsdall at tom@vanarsdall.com or (703) 509-4746.
From: "myrna miller" <mmill789@gmail.com>
Subject: Commentary - REPORT ...REALIZING / FULL POTENTIAL OF HEALTH INFORMATION TECHNOLOGY ...: THE PATH FORWARD
Date: Tue, January 4, 2011 11:05 am
To: pcast@ostp.gov

Thank you for a very enlightening and thought provoking report.

Attached are my comments compiled for this report.

Yours truly,

Myrna E. Miller, PMP, MS Information Systems
Dandi.Lion Solutions LLC,
(914) 428-4071

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  - Size: 479 k
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FROM: MYRNA E. MILLER

Commentary on Report:

REPORT TO THE PRESIDENT REALIZING THE FULL POTENTIAL OF HEALTH INFORMATION TECHNOLOGY TO IMPROVE HEALTHCARE FOR AMERICANS: THE PATH FORWARD
http://www.whitehouse.gov/sites/default/files/microsites/ostp/pcast-health-it-report.pdf

I’d like the members of PCAST to consider the following pros and cons of their report.

1. The methodology in a TOP-DOWN mega-data approach that is put forward in the report is to 
   **standardize first.** This sounds good, but in practice will then require –
   a. Extensive research
   b. Compilation of exhaustive technology solutions
   c. Decision on best-of-breed,
   d. Communicate that decision - allowing time for discussion,
   e. Study of alternatives and counter proposals,
   f. In an iterative fashion - amend and redistribute - until finally a majority or compromised order can be established on Health Information Technology for all peoples in these United States.

2. Health Information Technology (HI T) is different. The subject under scrutiny is: **Life or Death Choices** – a subject that cannot be taken lightly, nor assumed to be the purview of any one body or dictate. In many instances, the PCAST report compares HIT with other industries which assimilate technology without any mentionable disaster.

3. **Note:** Health information may not be extrapolated to fill in gaps as in bank statements missing over a period, or missing empirical economics readings over a period.

4. In the unusual scenario of life or death choices – consensus will be extremely difficult to solidify in an academic or ethereal realm – since, the mega-data, XML, proposition is still in its theoretical acceptance phase – while solutions have long already been built and deployed. Today’s leading edge technologists are already 10 – 15 years along this path.

5. The mega-data proposition is far too lofty a proposition, requiring vast academic consensus on whose approach is the best and brightest of the lot, and would stifle current competition, since all except the winner would need to discard current designs and restart. It would also lead to tremendous bottlenecking as people debate the pros and cons, the destination of the data and the different rights to access.

6. It might be the case that, when given the opportunity – less than one percent of American will make that choice to have their data submitted for trans-provider use in an EHR. Many have indicated to me that not only is there a real fear of losing, or “wiki-
leaking” confidential medical data to a potential college, nominating party, appointing board of directors, or soon to be spouse or adoptive parents – there is also the fear that accumulation of the data may lead to statistical predictions of diseases and “a health information” FICO score – with no input, knowledge or understanding from the subject. I daresay – let us not (hastily) forget the human categorizations that preceded the Holocaust....

7. Each practitioner will wish to translate his/her own individual methods into the practice, if he/she is to be held responsible for any and all decisions. They will likely be keeping paper and electronic for some time until they can develop trust. After all – a missing set of notes from Mr. Jones last heart attack 5 years ago could bring about an end of life, end of career and livelihood.

8. Finally, much is made throughout report of “patient directed” security, options, decisions, ability to participate. Yes – this does sound liberating at first glance. Do please remember – that unlike the customer at a bank, or merchandising kiosk at the nearby mall where such terms are enticing and heralds much freedom and choice – there is implicit in the Naming of a person as ‘patient’ that at some points – if not all – such persons must be assumed to have depreciated faculties, not of sound mind and body, and may not therefore be the best of class to make decisions on data information security, participation rules and preferences in those critical moments before open heart surgery!!!
Dear PCAST members,

The USDA supports research and development of critical interest to society, and produces a tremendous return on the investment. The commitment to form a National Institute of Food and Agriculture is an excellent recognition of that value. I wish to comment on one of the hallmark extramural research programs supported by the Institute, to highlight one way to maximize its benefit to the people of the United States.

Specialty crops (i.e. horticultural crops) represent half the value of US crop production and provide an enormous benefit to health and well-being. Research on specialty crops has far-reaching impact on societal needs in health, energy, urban society and other unobvious places. Programs that are part of the USDA Agriculture and Food Research Initiative must reflect that importance even more than they do today.

The following types of research are of particular importance to specialty crops.

* Basic research on processes that result in the high value of specialty crops, such as developmental regulation and secondary compound synthesis.
* Basic research on processes important for crop production, where the processes differ from model species of commodity crops. Stress resistance, pest resistance, developmental dysfunction.
* Agricultural-systems research suited to the high complexity of vegetable production systems, the perennial nature of fruit and ornamental production, or the synthetic nature of protected culture.
* Applied research to address specific substantial barriers to specialty crop production.
* Integrated programs to assure implementation and societal impact of solutions
developed with AFRI funding.

AFRI programs that support plant science should consistently include goals of relevance to specialty crops. AFRI program leaders with responsibility for those programs should be current on the issues for specialty crops in their areas of responsibility. Specialty crops needs should receive high weight in developing funding priorities. Knowledge of specialty crops issues should be a criterion in selecting AFRI panel managers and for populating panels.

Yours sincerely,

Thomas Björkman

Thomas Björkman  
Chair, National Issue Task Force, American Society for Horticultural Science  
Associate Professor, Department of Horticulture  
Cornell University  
Geneva, NY 14456

Attachments:

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From: "Jeanine Kennedy" <jea9ck@me.com>
Subject: Feedback on PCAST report from an HIT Policy Committee member
Date: Tue, December 28, 2010 10:29 pm
To: pcast@ostp.gov

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Message not printable

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The President’s Council of Advisors on Science and Technology recently issued a report on Information technology (IT) and the potential it has to transform healthcare. In this report, comparisons were made to the ability of IT to transform many other parts of the economy and
so, a similar potential must exist for health care. However, the article acknowledges that the impact of IT on healthcare has so far been modest even when fully implemented and that fully implemented, fully functional systems are rare. The Administration has been moving rapidly to promote the adoption by physicians and hospitals of electronic health systems through recent, important rule-making for 2011 and beyond. The President’s Council of Advisors on Science and Technology reviewed the work of the Administration such as the current Meaningful Use (MU) criteria and offered mid-course corrections and observations. They noted that in industries where IT has had a transforming effect, rapid progress has been catalyzed by “wise technology choices” that “open up markets to competition and innovation”. Many of the technology-related comments focus on “the standardization of simple universal methods for the exchange of information across multiple platforms and organizations”. The expectation is that universal exchange standards in health care will result in “network effects” and create a market for new products and services based on health IT. Thus, the paper concludes: since there is no “universal method for the exchange of information or no universal language, HIT has not yet lived up to its potential. Therefore, the creation of a universal language should solve the problem and allow the expected network effects to occur”.

This paper will offer support for 4 specific comments:

1. PCAST identified challenges should be addressed in Meaningful Use Phase 2
2. For “Network effects” to occur, end users must realize more value
3. A Universal Markup language is insufficient to create enough value for end users to embrace the HIT network; other policy, technical and business actions should be considered
4. Universal Markup Language efforts should be enhanced with efforts to create semantic interoperability and machine interpretable information

1. PCAST Identified Challenges Should be Addressed in Meaningful Use Phase 2

The PCAST report has correctly identified the most pressing and most fundamental gap in the current HIT policies. Health Information Exchange is unique in that it is clearly a weak link in the Federal HIT initiative to date yet is an absolute requirement for getting meaningful value from HIT. Most of the HIT objectives listed in the PCAST report as transformational HIT values cannot be obtained without secure, robust and meaningful health information exchange. However, transforming the PCAST’s constructive critique into policy does not require massive program changes; it can be accomplished by adaptation of the existing policies in the upcoming Meaningful Use Phase 2 criteria. The Meaningful Use phase 2 requirements currently under
development by the Meaningful Use sub-committee of the HIT Policy Committee can provide a clear signal to technology vendors, the physician and hospital community, and most importantly, patients. This signal would form a bridge—from the technology deployment focus of Meaningful Use Phase 1 to a clinical value focus in Meaningful Use Phase 2 (built on the foundation of the existing Meaningful Use Phase 1 requirements). This signal would be to embrace the current Meaningful Use Phase 1 and proposed Phase 2 requirements but to organize them around a single, clear goal: Attainment of a highly efficient, high quality care process for one or more specific chronic diseases. Given that chronic disease management accounts for up to 80 percent of health care spending, this approach would offer the nation its best opportunity to realize value from HIT deployment.

Value from technology deployment is never a given. Other industries that have been able to take advantage of technology have shown that deploying the technology in and of itself rarely creates the financial and quality gains possible from the technology’s use. Other functions inclusive of culture change, workflow modifications, financial incentives, strong leadership and many other functions often summed up as “Change Management” are required for maximal value from technology. Entire organizations such as consulting firms, business process outsourcers, and other companies exist to provide this expertise. Therefore, in order to create PCAST’s desired network effects, a path to value must be defined and established and reasons to focus a health care organization’s attention on walking down this path must be created. Don Berwick said it very clearly: “Without clear incorporation into the actual processes of care, and without re-engineering of those processes... “EMR initiative X” would become what far too many other health care organizations had already discovered in their own modernization journeys: the computerization of a defective status quo.”

Health care policy can focus the industry’s attention as the Meaningful Use Phase 1 criteria demonstrated. The Phase 1 criteria defined an industry floor that has created a tremendous amount of development and commercial activity by physicians, hospitals, technology vendors, health plans, and consulting companies. Billions of dollars are being invested to take advantage of the changes being created in the health care industry. This model can be directly applied to achieve the PCAST objectives through Meaningful Use Phase 2.

The current proposed measures for MU Phase 2 largely represent an extension of the current Phase 1 measures with certain Phase 1 optional measures becoming required in Phase 2, the thresholds on certain Phase 1 functions being increased in Phase 2, and a handful of new measures being introduced. Important components such as limited clinical decision support and structured lab results are new requirements in Phase 2. However, Phase 2 in its current form may not offer the best chance of value realization from the technology investment.

Phase 2 could be modified to begin to transform the HITECH initiatives from computer-deployment-based to value-based. Value would be defined as clinical improvements and/or care efficiency gains. Although this might initially sound like a tremendous increase in workload, workload effects could be managed by focusing the work around one or more disease states and not introducing significant additional requirements beyond what is currently envisioned for MU Phase 2. For example, a requirement could be added that all Meaningful
Use Phase 2 requirements should be satisfied by fully deploying Phase 2 functionality around a single disease state, generally a chronic disease. For instance, if a physician chose to focus on diabetes as his or her qualifying disease state for Meaningful Use Phase 2, then the structured lab results might only need to be blood sugars, Hemoglobin A1Cs, cholesterol tests, and a few others required to manage diabetes. The clinical decision support might only apply to diabetes management. The prescribing might only need to support diabetes treatments. Although most vendors would certainly focus on achieving an all-disease platform, the end-to-end evolution of an improved management capability will require many non-IT functions that could prove labor intensive if not narrowly focused. A collection of disease states where HIT is known to make a difference could be identified by ONC. For non-Primary Care providers, the specialty societies might develop recommendations where they feel HIT would offer benefit.

2. For “Network Effects” to Occur, End Users Must Realize More Value

The PCAST article identifies many significant barriers to Health IT adoption from proprietary systems to an administrative orientation to a lack of incentives for data sharing. However, one of the most fundamental challenges is not specifically referenced—in the case of Health IT, “free is not cheap enough.” Deployment of Health IT has many costs from the hardware and software to the training and support. However, eliminating some or all of those costs via Federal incentive payments ignores one of the most important financial challenges: productivity losses. Physician income is directly tied to productivity in our current pay for service (pay for volume of care delivered) system. Unfortunately, a productivity boost usually seen with the deployment of IT in other industries has eluded the health care industry. Increased physician documentation demands due to the heavy use of free text in EMRs is the industry norm. Productivity declines, especially during the first year of use are well documented. A recent study estimated the loss at ~$120,000 over the first year with over 80% due to losses in physician productivity. Strategies to reduce documentation demands such as technologies that convert free text to codes or more advanced still, technologies that use an ontology to make health care information understandable and manageable are not yet widely available. Therefore, current expectations for Health IT deployments generally include negative revenue and profit impacts in most deployments. Long term, physicians may recoup or even create a positive return from the investment but at least in the short term, from an economic perspective, free is not cheap enough.

Given this economic reality, further attention needs to be placed on the alignment of Meaningful Use Phase 2 as a path to mitigate these economic challenges. Again, a disease focused requirement for Meaningful Use Phase 2 might solve many of these problems. First, the technical development and workflow engineering could be focused around a specific disease in each environment, thereby limiting the amount of work required. A physician might choose to buy an EMR with a fully MU Phase 2 compliant hypertension module and just use the full functionality for his population of hypertensives. All Meaningful Use Phase 2 requirements including lab data capture, E-Prescribing, patient access to clinical management summaries, clinical decision support, as well as non-technical activities needed to optimally manage
hypertension could be aggregated and focused on achieving a particular clinical result. Further, the business process and workflow design issues could be concentrated around a single disease state with things like patient access to visit summary information linked together into a single, optimized workflow. Vendors would be motivated to develop compelling products (such as an end-to-end electronic diabetes care management program). New collaborations might form between physicians delivering the care and current health plan disease management programs that could offer additional manpower and coaching. New tools might be more commonly used such as bundled electronic glucometers which could be sold to patients for seamless, electronic diabetes management.

A Meaningful Use Phase 2 disease requirement would also begin to address the value realization challenges that must be resolved for network effects to occur by focusing physician and care giver attention where it needs to be—optimizing chronic disease or other care processes (rather than optimizing the number of electronic scripts that are sent). Natural discussions of workflow issues, patient support issues, performance reporting and analytics, and care management decisions would occur. For instance, a physician might look at his or her choice of EMRs and note that one had a patient support module that might increase the chance of his diabetics achieving a certain clinical and financial result. This kind of value creation offers interesting contracting opportunities for payers to embrace. It is a challenge for payers to directly pay for HIT because no direct value is obtained by the health plan. However, if physicians used HIT to optimize their disease management approaches and achieved certain quality and efficiency results, payers already have contracting strategies such as shared savings contracts, Pay for Performance modules, and pay for quality contracts, Patient Centered Medical Homes and many other approaches which allow physicians to financially gain from improved performance. Health plans could offer enrollment into disease management collaboration programs which would coordinate physician and patient care management with health coach activities. These improved programs would be sold for incremental revenue that could be shared with physicians further improving value realization.

A disease-focused requirement would also simplify and align reporting for Meaningful Use purposes. For instance, CMS could require detailed reporting on the physician-selected disease state allowing clear measures of value and progress centered on something everyone understands—that effective management of chronic disease creates value for the individual and for the country. Existing quality measures as defined by current HIT Policy Activities could be grouped by disease state. Standards could be set or voluntary goals established which would provide an organizing principle for physicians and patients alike. Disease management effectiveness of vendor programs might even form a basis of competition and help drive the desired network effects. Disease state measures would also have commercial value to physicians and plans and begin to form a rational basis for transparency programs. Transparency would reward high quality, efficient and effective care processes and create incentives for the improvement of less effective processes, resulting in evolutionary momentum toward a high quality, efficient health care industry.
In conclusion, aligning economic incentives of the network end users (physicians and other providers) is key to achieving network effects and Health IT value. A greater focus on productivity impacts, workflow changes, and disease-specific Meaningful Use criteria could be a helpful addition to moving us toward the value HIT promises.

3. A Universal Markup Language Is Insufficient to Create Enough Value for End Users

The PCAST recommendations call for Health Information Exchange technology to help improve the likelihood of getting value from HIT. Specifically, a Universal Markup Language is argued to:

“manage and store data for advanced data-analytical techniques is to break data down into the smallest individual pieces that make sense to exchange or aggregate. These individual pieces are called “tagged data elements,” because each unit of data is accompanied by a mandatory “metadata tag” that describes the attributes, provenance, and required security protections of the data. Universal exchange languages for metadata-tagged data, called “extensible markup languages” are widely and successfully used. ONC’s clinical document architecture standard (CDA) is such a markup language, and is an important step in the right direction. The indexing and retrieval of metadata-tagged data, across large numbers of geographically diverse locations, is an established, highly developed, technology—the basis of web search engines, for example.”

This approach has certain limitations that will impede the creation of maximal value from Health IT. The easiest way to visualize the PCAST recommendation is to think of the Internet, something most use routinely. The Internet uses markup languages to provide end users with very rich experiences. We execute commerce, bank, are entertained, and receive much of our news over the Internet. But such applications generally fall into one of two paradigms:

- E-commerce which uses financial functions that are highly suited to computerization because the unit of measure is money (dollars). Dollars can be added, subtracted, multiplied, converted, analyzed... all via computerized operations
- Presentation of information on a web page which requires human intelligence to consume the interaction

Neither of these paradigms will create the expected value from Health IT. The reasons are extremely simple:

- clinical care is not based on e-commerce but on “clinical commerce” which does not use money or dollars as its unit of measure but clinical information. Clinical information is largely free text and cannot be added, subtracted, analyzed... in its current form
- Reading a clinical record composed of web pages versus reading a clinical record composed of paper does not create sufficient incremental value to create network
effects and other anticipated value. A markup language may create a better record but a better record in and of itself won’t create the value the industry needs.

A real, but extremely simple health care example highlights the limits of mark up languages:

Imagine a patient who receives a prescription—“On December 16th, 2010, Dr Kennedy gave Miss Smith a prescription to take one Augmentin 250mg tablet three times a day”

Using a Universal Markup Language as recommended by PCAST or as currently defined in CCD specifications, the information might be shown as follows:

```xml
<Prescription>
  <Patient> Mrs Smith </Patient>
  <Date> 25 Sep 2008 </Date>
  <Doctor> Dr Jones </Doctor>
  <Medication>
    <Term> Co-amoxiclav 250mg/125mg dispersible tablet sugar free </Term>
    <Ingredient>
      <Drug> Amoxicillin </Drug>
      <Amount> 250 mg </Amount>
    </Ingredient>
    <Ingredient>
      <Drug> Clavulanic Acid </Drug>
      <Amount> 125 mg </Amount>
    </Ingredient>
  </Medication>
  <Instruction> one 3 times a day </Instruction>
</Prescription>
```

As referenced by the PCAST report, this type of approach would allow one to send information from a system with each data element tagged (as shown above) with an interpretation or explanation (known as metadata) of what the data element is. The receiving system would be in a position, assuming the data standards are tight and specific enough (which they are not) to unpack this message and put it into the database of the receiving EMR. A medication could be added to a list of medications in the master medication list of the receiving EMR. A lab result could be added to a database of lab results. The physician would then be in a position to open up his EMR and have a list of every known medication, every known lab, and every known radiology result for a particular patient.

However, this achievement misses several important functions necessary for value creation from Health IT. For instance, a universal markup language could create more comprehensive records for physicians to sift through. However, the sheer additional volume of data—without being sorted, organized, or more easily searchable than by date or department (e.g., lab or medication) will likely frustrate busy physicians, reduce system use, and could actually deter
value realization. Further, a universal markup language does not provide a compelling foundation for algorithms (both real-time and post hoc) to run—a necessary requirement for achieving maximal value from Health IT. Other problems that are both technical and functional in nature but are not resolved by a universal markup language include:

- If every medication the patient has taken is transmitted via a Universal Markup language, multiple duplicate entries will occur. For instance, the same antibiotic might be listed multiple times—from the claim data, the retail pharmacy, the EMR, the Practice Management System, a second Retail Pharmacy...or the physician might have prescribed a multi-month prescription and then re-prescribed it without regard to remaining refills. Without sophisticated data management capabilities, physicians will get reams of data but very little information. A stack (or screen) of data with tens or hundreds of entries on it will have limited usability and value. A Universal Markup language in and of itself will not solve this problem.

- The data will not have formal meaning. In other words, when a markup language is used, it may have a description of what the data is sufficient to put the information into a bucket of information called “medications” or “labs”. This is a step forward over pure free text. However, a mark-up language does not create a consistent, unchanging meaning of the information suitable for achieving “semantic interoperability” and that is what is most needed. For instance, a markup language can tell that Augmentin is a medication by describing it as a medication in the metadata of the data stream. But, the markup language would not convey that Augmentin is composed of amoxicillin, a type of penicillin and clavulanate which is a type of antibiotic-enhancer which is a type of medication. That hierarchy requires codes—a coding schema such as NCPDP or RxNorm and an understanding of how to apply that coding scheme to an individual’s set of drugs. Achieving semantic interoperability—that is creating a consistent meaning of the data as it is moved from system to system in a way that the computer system understands is consistent is a requirement for fundamental HIT values such as decision support, creation of a master medication list, and ensuring care is consistent with the evidence base. Although certain things like drugs are fairly well codified, most health care data is not. This includes things like physical exam findings, past medical history, even much of the lab data—even when reported with LOINC coded metadata tags.

- A markup language does not directly support the storage, transmission, or uploading of data in a coded format that attaches consistent meaning. Such coded data is necessary for computer systems to perform operations that can begin to take advantage of the computational power of modern information system design. Operators join concepts and define relationships: and, that, some, only, or, value and equivalentTo. A set of operators (rules) for how the data structure is to be interpreted is called a Description Logic. By combining a consistent meaning to the data and data structure with a standard set of how the data structure is to be interpreted imparts huge power to the computer. Armed with some formal meaning the computer can really start to help. This is the key to putting data to use—formal meaning, coded data, and description logics. This is
especially critical as data volume increases due to Health Information Exchange and the need to sort through larger data volumes and present them in a consumable format increases.

In summary, a Universal Markup Language provides some helpful capabilities but still leaves multiple critical challenges to be resolved.

4. Universal Mark Up Language Efforts Should Be Enhanced with Efforts to Create Semantic Interoperability and Machine Interpretable Information

The PCAST report highlighted the importance of Health Information Exchange in achieving transformational value from HIT. However, this report should be put into context with another compelling academic review of HIT value from the National Research Council published in February of 2009. This paper identified some of the same challenges but focused their recommendations around the value of providing cognitive decision support to improve patient care value. Cognitive decision support designed to avoid errors and inefficiencies by influencing physician and patient decision making in care management functions was seen as the fundamental link in getting transformational value from Health IT. The reality is that both of these reports point to a shared set of challenges that must be overcome in order to create “transformational” health care value:

- Health Information Exchange is necessary to create a comprehensive patient record
- A comprehensive patient record is foundational for cognitive decision support
- Cognitive decision support requires semantic interoperability with machine interpretable data

These three concepts represent a foundation upon which a modern national health care delivery system that uses Health IT to achieve better clinical and financial results should be built.

Health Information Exchange is an essential component in creating a comprehensive electronic patient record. Most patients in most communities do not receive their care from a single entity such as an integrated delivery system. Most patients, especially those with chronic disease suffer from a high illness burden and receive their care from multiple physicians and caregivers in multiple organizations. Sharing data across organizational walls inclusive of all of
the patient’s care team is the only way to create a virtual care delivery system, centered on each individual patient.

However, Health Information Exchange in and of itself does not provide the needed information for patient-centered care coordinated through an extended or virtual care team. Many current exchanges simply use secure messaging to move a summary document (e.g., a CCD) from system to system. As the PCAST report indicates, this type of document-level exchange is unlikely to provide the needed information at the specificity or granularity needed for individual members of the extended care team to act upon. Current exchanges frequently require physicians to sort through a massive stack of messages — opening each one up to see if it has information that is relevant to the clinical condition the physician is treating at that particular moment. Although some exchanges are able to indicate whether the secure message is a transcription or a lab result or a radiology result, health information exchanges of today typically are not able to sort information by disease state, such as presenting all of the information associated with diabetes whether it is a lab result or a dictation or an X-ray result. The lack of a more sophisticated data management infrastructure is in part what the PCAST report is pointing to in its recommendation of a universal markup language. One would assume that a universal markup language would enable systems to interpret what the information being delivered is and place it correctly in the user interface of the receiving system; as shown above, metadata tagging is not sufficient. Additional steps that allow one to do important tasks such as presenting the information in a way that physicians think about patients (such as by disease state) or presenting the information in ways that patients can use it (layman view) are essential to achieving Health IT value

The important next step is using the resulting comprehensive record for cognitive decision support. Cognitive decision support involves the use of computerized algorithms that allow the computer to make care suggestions such as reminders or alerts, relevant to the specific patient and their specific care situation at the time when such recommendations are most useful. These algorithms are most advanced in pharmaceutical management processes where coding is most comprehensive. In the Pharma environment, many elements necessary for safety or efficiency algorithms to run are possible. The medication, quantity, days supply, refill status, cost, and many other measures are either numerical or coded (sig being the major exception, leading to its own set of issues). This makes drug data more amenable to safety or efficiency algorithms. If, then, and, that, some, only, or, equivalentTo operations can easily be applied to significant parts of the coded Pharma data. Moving beyond pharmacy data, however, results in a challenge—the data moved in HL-7 messages or resident in EMRs are typically so unstructured and/or uncoded as to need to be treated as free text. Existing technologies to convert this free text to codified data are in their infancy. Most EMRs do not require physicians to use any type of coding schema to document their clinical findings; coding is applied for billing
after the care has been delivered. An extensible markup language will not solve this challenge. Electronic medical records composed of information integrated from other systems using the proposed markup language might present information more effectively to a human end user if the volume and duplication issues discussed above can be solved. But, they will not provide a foundation for clinical decision support and do not in and of themselves allow the computer to assist the provider with decision making. The PCAST reports proposes linking the markup language to medical vocabularies—SNOMED might be one—but, for example, the current implementation of SNOMED does not have the appropriate canonical representation necessary to consistently arrive at comparable data or to algorithmically map all other classifications, thus forcing the use of other schemes.

In other words, the linking of medical terminologies to a markup language leaves multiple challenges unresolved such as semantic appropriateness of the underlying terminology, operations to map the free text to the medical terminology, ambiguous meanings in the medical terminology, and mismatches between the label of a particular concept and its formal meaning. In order to fully resolve the problems identified in the PCAST and the NRC reports, a broader and more comprehensive approach to the challenge of information exchange, data management, and cognitive decision support is required. In recognition of this challenge, the Administration should offer additional flexibility in the entities that are commissioned to achieve Health Information Exchange and cognitive decision support. Instead of a focus on an extensible markup language, a broader focus should be embraced inclusive of how to create a way of translating existing HL-7 messages into a codified and understood form, understanding the needs of an appropriate medical terminology and medical ontology for semantic interoperability, and applying these concepts to clinical care delivery. Narrowing the focus to a particular set of chronic disease states might offer an initial step forward. Once that is accomplished, other technologies (inclusive of a markup language) could be included to help with presentation purposes. But broadly describing the problem as solving the task of enabling a computer to have an electronic understanding or framework of a particular patient’s disease state, the current treatment approaches, and the optimal evidence based interventions is more likely to result in a positive outcome than a markup language. Actions to incent multiple initiatives to develop this kind of machine readable language should be rapidly undertaken.

In conclusion, the PCAST paper makes multiple important observations which HHS, CMS, ONCHIT, the HIT Policy and Standards committees and Health IT entities overall should take note of. However, its proposed solution of a Universal Markup language will not take us far enough to achieve the network effects and new business services that the paper hopes will come into being. For that to occur, we must create the equivalent of E-Commerce for health care—call it clinical commerce. Clinical commerce cannot be realized with a mark up language. Clinical commerce can only occur when the complete advantages of computers can be utilized in clinical medicine. These advantages are centered around clinical data that computers can use to compute with. Computable clinical data requires semantic interoperability and machine readable information. ONCHIT should expand the call for a Universal Mark
Up Language to include these capabilities. This effort should be complemented with an effort to mobilize clinical data sources including labs, radiology, and other clinical data sources a physician would embrace in their management of patients. Because mobilization of clinical data from the hundreds of thousands of data sources is a massive task, ONCHIT should manage the scope of these activities around disease states starting with the chronic diseases that drive the majority of health care spending. The result should be a new platform for clinical care centered around patients and their particular disease states embraced on a region by region level with measurable results that can demonstrate the value of the nation’s investment.
On behalf of 58 international organizations from civil society, I would like to submit the attached letter to the President's Council of Advisors on Science and Technology for review during the Council's January 7th meeting. The letter was originally submitted on December 16, 2010 to the Presidential Commission for the Study of Bioethical Issues in response to their report on synthetic biology. These organizations do not support the Commission's recommendations on synthetic biology. The recommendations are an inadequate response to the risks posed by synthetic biology because they: 1) ignore the precautionary principle, 2) lack adequate concern for the environmental risks of synthetic biology, 3) rely on the use of "suicide genes" and other technologies that provide no guarantee of environmental safety, and 4) rely on "self regulation," which means no real regulation or oversight of synthetic biology.

I would be happy to answer any questions the Council may have regarding this letter and our concerns. I will be at the January 7th meeting but unfortunately I accidentally clicked "no" when asked if I want to comment publically. I would appreciate the opportunity to speak for 1-2 minutes to highlight the concerns raised in this letter.

Sincerely,

Eric Hoffman

Friends of the Earth

202.222.0747
Dear Dr. Gutmann,

Thank you for this opportunity to comment on the Commission’s recommendations on synthetic biology. We applaud the transparency and openness of the Commission’s deliberations. Unfortunately, this process has not resulted in recommendations that recognize the serious threats synthetic biology pose to the environment, workers’ health, public health, and social justice.

The undersigned 58 organizations from 22 countries do not support the Commission’s recommendations on synthetic biology. They are an inadequate response to the risks posed by synthetic biology because they: 1) ignore the precautionary principle, 2) lack adequate concern for the environmental risks of synthetic biology, 3) rely on the use of “suicide genes” and other technologies that provide no guarantee of environmental safety, and 4) rely on “self regulation,” which means no real regulation or oversight of synthetic biology.

A precautionary regulatory framework is necessary to prevent the worst potential harms. This requires a moratorium on the release and commercial use of synthetic organisms until a thorough study of all the environmental and socio-economic impacts of this emerging technology has taken place. This moratorium should remain in place until extensive public participation and democratic deliberation have occurred on the use and oversight of this technology. This deliberative process must actively involve voices from other countries - particularly those in the global South – since synthetic biology will have global impacts and implications.

The Precautionary Principle Should Guide Synthetic Biology Regulations
The Commission’s recommendations fail to implement the precautionary principle, and instead referenced the so-called “prudent vigilance” concept. The precautionary principle is recognized by
international treaties including the United Nations Convention on Biological Diversity, the Cartagena Biosafety Protocol, the new Nagoya/Kuala Lumpur SubProtocol on Liability and Redress for Damages Due to the Transboundary Movement of Transgenics, and the UN Framework Convention on Climate Change. Although "prudent vigilance" is used as a guiding principle by the Commission in its recommendations, it is a completely new concept, apparently invented by the Commission without legal or policy precedent. When dealing with novel synthetic organisms that pose serious risks to the environment and public health, we cannot rely on a new concept with no agreed upon definition, framework, or precedent.

The precautionary principle often is mischaracterized as anti-science, anti-technology, or anti-progress. This is far from the truth. The precautionary principle, as outlined by the Wingspread Consensus Statement on the Precautionary Principle, states: "When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically. In this context the proponent of an activity, rather than the public, should bear the burden of proof. The process of applying the Precautionary Principle must be open, informed and democratic and must include potentially affected parties. It must also involve an examination of the full range of alternatives, including no action."

Precaution does not derail progress; rather, it affords us the time we need to ensure we progress in socially, economically, and environmentally just ways. In the face of uncertainty and the potential for serious harm, synthetic biology will often require risk analysis. We do not yet know what the full environmental or socio-economic risks of synthetic biology are, nor has our regulatory system evolved to keep up with the science. That is why we need a precautionary approach.

Precedent exists within the executive branch to support the use of precaution. The President’s Cancer Panel released a report in April 2010 on reducing environmental cancer risks, recommending that:

"A precautionary, prevention-oriented approach should replace current reactionary approaches to environmental contaminants in which human harm must be proven before action is taken to reduce or eliminate exposure. Though not applicable in every instance, this approach should be the cornerstone of a new national cancer prevention strategy that emphasizes primary prevention, redirects accordingly both research and policy agendas, and sets tangible goals for reducing or eliminating toxic environmental exposures implicated in cancer causation..."

This should be a guiding precept for the Presidential Commission for the Study of Bioethical Issues.

In October 2010 at the United Nations Convention on Biological Diversity (CBD), 193 nations unanimously agreed to apply the precautionary principle to the introduction and use of synthetic organisms. The CBD also recognized this technology to be a potential environmental threat in need of further review -- particularly as it is applied to biofuels production. This was the first time the United Nations addressed the issue of synthetic biology; ignoring this important decision would be negligent.

**Lack of Environmental Risk Assessment**

The Commission’s lack of attention to ecological harms posed by synthetic biology is irresponsible and dangerous. The only ecologist to speak to the Commission, Dr. Allison Snow, raised serious concerns about the environmental risks of synthetic biology -- but none of these concerns are reflected in the recommendations.
In her testimony, Dr. Snow presented four cautionary precepts to keep in mind about the ecological risks of synthetic biology and novel genetically engineered organisms (GEO):

1) “We need to be very careful whenever novel, self-replicating organisms are let loose in the environment (intentionally or by accident). Many will do no harm out in the environment, but important exceptions could occur, especially if the GEO can multiply and become more abundant.

2) Novel GEOs that seem innocuous or weak might evolve to become more successful when they start reproducing. Even if they are highly domesticated, mutations or unexpected properties might allow them to multiply in some environments.

3) Once these organisms are released into the environment, novel GEOs cannot be taken back.

4) Predicting which new organisms might cause irreversible harm can be extremely challenging... we have little or no experience with cultivating microalgae and bacteria outdoors, let alone new life forms that are entirely synthetic.iv

These points are mostly ignored in the guidelines.

The potential environmental impacts of the commercial use of organisms with synthetic DNA must also be examined. Many commercial applications of synthetic biology will undoubtedly lead to the environmental release of synthetic organisms – since it is impossible to prevent organisms from escaping from unsecured operations conducting activities described by some synthetic biology proponents as “akin to brewing beer.”v More study also is needed on the risks of introducing synthetic organisms into the human body for biomedical and health-related applications, as well as on the risks posed by uses of synthetic organisms in agriculture. Since this technology is already being used to replicate pathogens, serious study of biosecurity risks is also necessary.

Even more troubling is the impact that synthetic biology could have on ecosystems and communities in the global South. A new “bioeconomy,” in which any type of biomass can be used as feedstock for tailored synthetic microbes, is being enabled by synthetic biology. Biomass to feed synthetic microbes will be grown mostly in the global South, disrupting fragile ecosystems and exacerbating environmental damage from industrial crop production. Further pressure will be placed on land and water, which already are in short supply for food production, to produce fuels and chemicals that will be consumed mainly by wealthier nations. The Commission ignores these socio-economic and environmental harms despite the fact that already countries such as Brazil have felt their effects.

Unfounded Reliance on “Suicide Genes”

Despite the fact that “suicide genes” were explicitly described as having uncertain efficacy in Dr. Snow’s testimony, the Commission relies solely on these and other types of self-destruction modalities as the main form of mitigating potential environmental harm. In fact, one of the main studies cited by the Commission in support of using methods to create “suicide genes” is still in an early development stage and has not been field tested.

Scientists who have studied “terminator technologies” in seeds have concluded that the process is never completely effective. They found that frequently occurring mutations allow organisms to overcome the intended sterilization thereby allowing those organisms to remain viable. Specifically, “suicide genes” and other genetic use restriction technologies (GURTs) represent an evolutionary disadvantage; selective pressures will lead organisms to overcome intended biological constraints.vi Biological
containment of synthetic organisms – which reproduce quickly, escape confinement, and cannot be recalled – is impossible.

Importantly, the UN Convention on Biological Diversity has mandated an international moratorium on the use of “terminator technologies” such as “suicide genes,” and other GURTS that has been in place for the past decade. Reliance on an unproven technology that has been deemed unacceptable by 193 nations as the main method to “contain” synthetic organisms is irresponsible.

Reliance on a technology that will not guarantee biosafety or biosecurity and that has been prohibited by the international community is not a solution. Synthetic biology requires the strictest levels of physical, biological, and geographic containment as well as independent environmental risk assessment for each proposed activity or product.

**Self-Regulation Amounts to No Regulation and Undercuts the Rights of Workers and the Public**

Self-regulation cannot be a substitute for real and accountable regulatory oversight. Some synthetic biologists already have made several unsuccessful attempts at self-regulation. The second annual synthetic biology conference in May 2006, SynBio 2.0, was portrayed by proponents as “Asilomar 2.0,” in reference to the 1975 meeting that proposed voluntary guidelines on recombinant DNA. At the 2006 meeting, synthetic biologists attempted to write a set of self-regulations intended to protect the environment and promote the field. This conference failed to produce serious results. Synthetic biologists were too concerned about promoting research and development to agree on even weak attempts at self-regulation.

The lack of open dialogue with concerned parties also contributed to the failure of the industry’s attempt at self-governance. Civil society and the public, blocked from participating in these discussions of self-governance, issued an open letter to the conference participants. Signed by 38 organizations working in 60 countries, this letter called on synthetic biologists to abandon their proposals for self-governance and to engage in an inclusive process of global debate on the implications of their work.

The current state of “self-governance” permits students to create synthetic organisms on campuses; and stretches of synthetic DNA may be purchased online, allowing laypeople to create organisms in their garages where, with no oversight, life forms not previously found in nature may be dumped down drains and flow, freely, into the environment.

The J. Craig Venter Institute and the Massachusetts Institute of Technology also attempted to draft self-regulations the following year in their report, *Synthetic Genomics: Options for Governance*. This report was limited in scope to biosecurity and biosafety in laboratory settings, focused solely on the U.S., and, importantly, completely avoided the topic of environmental safety. These experiences reinforce the need for real oversight to ensure that the real threats synthetic biology poses are never actualized.

The support of the Presidential Commission for the Study of Bioethical Issues for self-regulation undercuts the fledgling efforts of the Occupational Safety and Health Administration (OSHA) to put new safety requirements in place to protect workers using biologically engineered materials, nanomaterials, and novel organisms. The Commission’s support for self-regulation undercuts the ability of workers to speak out and protect themselves. Becky McClain, a former Pfizer scientist, recently won the first lawsuit regarding a worker’s right to discuss publicly the health and safety issues of the genetic engineering laboratory. The Commission’s failure to support lab scientists’ basic right to know which synthetic organisms they may have been exposed to means those workers could become ill without
being able to inform their doctors of the potential causes of their illness. There is nothing “ethical” about this kind of self-regulation.

**Conclusion**
The Commission’s recommendations fall short of what is necessary to protect the environment, workers’ health, public health, and the public’s right to know.

We repeat our call for a moratorium on the release and commercial use of synthetic organisms until we have a better understanding of the implications and hazards of this field and until we have properly updated and effectively implemented public regulation of synthetic biology.

The time for precaution and the regulation of synthetic biology is now.

Sincerely,

African Biodiversity Network (Kenya)
African Centre for Biosafety (South Africa)
Alliance for Humane Biotechnology
Amberwaves
Asociación para la Promoción y el Desarrollo de la Comunidad CEIBA / Friends of the Earth Guatemala
Associação para do Desenvolvimento da Agroecologia (Brazil)
Biofuelswatch
Center for Environmental Health
Center for Food Safety
Center for Genetics and Society
Centro Ecológico (Brazil)
COECOCEIBA-Friends of the Earth Costa Rica (Costa Rica)
Columban Center for Advocacy and Outreach
Columban (Missionaries) Justice, Peace, and Integrity of Creation Office (Australia)
Development Fund (Norway)
Ecumenical Ecojustice Network
Edmonds Institute
Environmental Rights Action/Friends of the Earth Nigeria
ETC Group (Canada)
Food & Water Watch
Friends of the Earth Australia
Friends of the Earth England Wales and Northern Ireland
Friends of the Earth Canada
Friends of the Earth Cyprus
Friends of the Earth Spain
Friends of the Earth Uganda
Friends of the Earth U.S.
GE Free New Zealand
Gene Ethics, Australia
GeneWatch UK
GLOBAL 2000/Friends of the Earth Austria
Groundwork/ Friends of the Earth South Africa
It is critical that research, education, outreach, and extension activities be supported by the federal administration. The U.S. is in one of the precarious positions it has been in through its history. Food scarcity is an issue. We have gone from a net exporter to a net importer of a number of critical commodity crops. The need for energy is competing with the need for food production. Without agricultural research, education, outreach, and extension activities provided through the land-grant university system of the U.S., we will not be able to provide food for our own citizens, let alone those in other countries.

Carol E. Lewis

Attachments:

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01/14/2011 - 1:40pm  Krukov  general_krukov@abv.bg  PCAST

Spacecraft, gravity, curvature of space and time  Circular flux is created in a special system prisms with total internal reflection. Powerful laser and special optics. Accumulated light energy reaches the required level and distorts the continuum. Spacecraft overcome space with this technology. Time travel is impossible. Gravity change only the local time. Free energy Electromagnetic waves emitted by the antenna in a closed metal box. The size of the box is less than half the wavelength. Waves are shortened by quantum mechanics. Their energy increases to the minimum energy for the size of the box by quantum mechanics. These waves are taken with appropriate antennas in the box. N. Tesla used this technology for its renowned car with free energy in 1931. http://krukov.hit.bg/ by http://krukov.hit.bg/bg.html

01/14/2011 - 1:40pm S. Orlene Grant  The Grant Group, LLC  301 325 8850 sogrant@thegrantgroup-llc.com  PCAST

Is it possible to listen during the next PCAST

01/14/2011 - 1:46pm Tim Williamson  self  1-205-765-6090globaleconomy101@gmail.com  PCAST

Education & Economic Sustainability in the US see the file below. Thanks! Tim Williamson

01/16/2011 - 1:11pm  Jane Jackson  Arizona State University  480-965-8438  jane.jackson@asu.edu  PCAST

(I tried three weeks ago to submit this by OpenPCAST, but failed. It is poor, compared to comparable open forums like that of the AAAS. ) I submit this now because the Obama Administration's newly released plan to produce 100,000 world-class STEM teachers omits the most important action: inservice STEM teacher development. The Modeling Instruction Program at Arizona State University has done teacher development for two decades. Three thousand physics and chemistry teachers have taken Modeling Workshops. Physics professor David Hestenes founded Modeling Instruction; you know him, perhaps, as the author of the Force Concept Inventory. At the PCAST meeting on January 7, NSF Director Subra Subesh remarked on two trends: top students in India no longer choosing careers in science and engineering (true in the United States too); and top Indian scientists and engineers choosing not to come to the United States. The U.S. must produce its own scientists and engineers again, or else our nation will face a severe shortage of scientific and engineering professionals and technical workers. The problem starts in K-12 education. High school physics is crucial, for physics is the foundation of engineering, technology, and other branches of physical science, and physics is prerequisite for
biological and medical sciences. Progress in improving high school physics is thus essential to our national interest. Yet relatively few students take high school physics; the quality of conventional instruction is poor; and a shortage of qualified physics teachers exists. These three problems are endemic in chemistry, too, although not quite as severe. The Modeling Instruction Program at Arizona State University addresses these three problems by providing research-validated professional development for teachers of the physical sciences. See http://modeling.asu.edu/ Many teachers report that a larger percentage of their students choose STEM majors in college than before they began using Modeling Instruction. Anecdotal reports by teachers are at http://modeling.asu.edu/SuccessStories_Mi.html. For example, Carmela Minaya, a chemistry teacher in Hawaii who took Modeling Workshops at ASU in three summers, wrote: "I have several [former] students who are majoring in science related fields largely due to the implementation of Modeling Instruction in my classroom. The percentage has gone up from 13% (pre-modeling) to 51% in more recent years." A large-scale study of this effect was done in 1999: Modeling Instruction was one of six NSF-funded high school physics "reform" programs evaluated by TIMSS (Gonzalez, 2000; in pdf at http://modeling.asu.edu/Evaluations/Evaluations.html). The report documents that the reform programs greatly increase the percentage of students pursuing STEM careers. In particular 40% of 12th grade students in reform programs intended to major in physics, math, engineering or computer information sciences in college, compared to 25% in non-reform programs. On Science and Math Literacy tests, the reform programs scored highest in the world! Unfortunately, the NSF stopped funding teacher enhancement. Current NSF EHR policy is to do only research and development (R&D). This is a big mistake that will hamper America's competitiveness. The NSF should take another turn on the spiral and fund RESEARCH-VALIDATED teacher enhancement. STEM TEACHER DEVELOPMENT IS FAR MORE IMPORTANT THAN INITIAL TEACHER PREPARATION. WE HAVE SHOWN THAT. See my Sept. 2010 publication, referenced below, and also an article in press for the American Journal of Physics, lead author David Hestenes. The best legislative action, we believe, would be to require the NSF to implement the top recommendation of the K-12 Focus Group of "Rising Above the Gathering Storm". Those Focus Groups were charged to come up with the "top three actions the federal government could take so that the United States can successfully compete, prosper, and be secure in the global community of the 21st century" (NRC, 2005). The K-12 Focus Group's top recommendation, which has not been implemented, is: "The federal government should provide peer-reviewed long-term support for programs to develop and support a K-12 teacher core that is well-prepared to teach STEM subjects. a. Programs for in-service teacher development that provide in-depth content and pedagogical knowledge; some examples include summer programs, Master's programs, and mentor teachers. b. Provide scholarship funds to in-service teachers to participate in summer institutes and content-intensive degree programs. c. Provide seed grants to universities and colleges to provide summer institute and content-intensive degree programs for in-service teachers." The U. S. Department of Education could help too, if the impending ESEA reauthorization included an IMPROVING TEACHER QUALITY (ITQ)-like program that gives priority to high-need STEM subjects and that encourages long-term grants and interstate cooperation. The U. S. DoEd ITQ program is intervention/teacher enhancement or development, as opposed to R&D, and is thus cost-effective -- which is crucial in this economic downturn. I have had ITQ grants for several years; an ITQ grant can serve FOUR TIMES AS MANY TEACHERS as an NSF Math-Science Partnership grant.
Unfortunately, indications are that the DoEd intends for the current ITQ program to die. That will be a disaster for physics and chemistry teacher development. Their only other teacher development program, the state MSP program, is designed for K-8, not for high school. I am finding it impossible to apply for a state MSP grant for physics and chemistry teachers -- regulations are unworkable for this group of teachers. These recommendations and related ones are discussed in my published article, "Arizona State University's preparation of out-of-field physics teachers: MNS summer program" (Summer 2010 issue of Journal of Physics Teacher Education Online, at http://www.phy.ilstu.edu/jpteo/). I hope you read it. Sincerely, Jane Jackson, Co-Director, Modeling Instruction Program Department of Physics, Arizona State University, Tempe

01/17/2011 - 2:39pm Luke Ho-Hyung Lee Ubiquitous Market System 805-341-5884 luke. h. lee@gmail. Com

"Please forward this message to Chief Technology Officer Aneesh Chopra in the Office of Science & Technology Policy" Dear Mr. Chopra, My name is Ho-Hyung (Luke) Lee. I am the president of Ubiquitous Market System, a Los Angeles company specializing in ubiquitous marketing. Even if it proved necessary for the modern information market, no efficient information-based supply chain INFRASTRUCTURE has ever been developed in the real distribution (supply chain) processes of the market. I believe this is the real cause of the current economic crisis. According to my simulation, if this infrastructure is quickly, effectively and fully developed and implemented in the market, we could create more than 5 million new jobs within 5 to 7 years in the US market alone. I believe this is one of the most viable and effective paths for the current economic crisis. I would strongly suggest you see this article for more details: "Breaking Down the Economic Death Spiral - and Saving the World Economy" http://t. co/8pMwQh7 If you have any questions, please feel free to contact me. Sincerely, Luke Ho-Hyung Lee Ubiquitous Market System luke. h. lee@gmail. Com

01/17/2011 - 7:11pm Dennis R. Karote NanoScale Corporation 7855370179X159 dkarote@nanoscalecorp. com PCAST

Hi, I am requesting permission to reproduce the Figure 3-1 of March 12, 2010 "Report to the President and Congres on the Third Assessment of The National NanoTechnology. Please advice me procedure to get the permission. Thanks

01/18/2011 - 1:38am Robert Tinker The Concord Consortium 978 405 3222 bob@concord. org

I was on the PCAST STEM education panel and was particularly excited about the STEM-Ed idea. I was delighted to see it in the President's budget. Do you have any advice on how I can help generate support for this, or is it DOA given the climate in DC?
My name is Stephen Ambrose. I have met before with Mr. Chopra, when he was serving in Richmond, VA. I have an excellent technology fit for the current issue of malpractice and tort reform, which would allow the President to address this and not change his position with the legal community. Please call me as I would like to discuss the patent-pending technology, for use with both the health, P&C and malpractice industries. Thx, Steve Ambrose (804) 929-8804