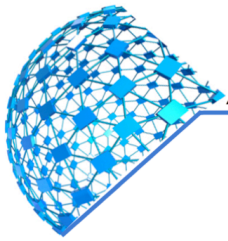

The Medical Billing Framework as the Backbone of the National Health Information Infrastructure

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ABSTRACT

Given the medical billing framework and proposed meaningful uses for the national health information infrastructure, this paper shows how the billing framework can strategically help achieve meaningful uses quickly.

The existing medical billing framework has national connectivity, and its existing communication, data, and authentication standards are sufficiently expandable to serve as a necessary backbone for a national health information infrastructure. Doing so offers strategic advantages: (1) providers are already "wired" and using the billing framework, processing billions of claims a year; (2) the mechanism to check patient insurance eligibility can easily expand to additionally provide relevant patient information (e.g., problems, medications, and allergies) at the time and place of service; (3) a national program already exists that captures quality measures through claims processing; and, (4) payment incentives on claims can drive ongoing provider compliance. Growing independent regional data centers, as has been the primary focus so far, leaves a critical gap in connectivity, data consolidation, national analytics, and timeliness. To close the gap, this paper proposes an amended billing framework ("the Backbone"), and shows how the Backbone can help achieve meaningful uses. It recommends an open consortium of stakeholders to guide ongoing Backbone operations to insure interoperability. Included are detailed examples of maintaining active allergy and medication lists (a meaningful use objective for the year 2011).

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Medicare processes 1.2 billion claims per year [1] on the medical billing framework, so this paper was written for the Centers for Medicare and Medicaid Services (CMS) in response to CMS' Request for Information dated August 20, 2009, entitled "National Gap Analysis and Readiness Assessment for the Health Information Technology Infrastructure to Enable the Electronic Exchange of Quality Measures as part of EHR Meaningful Use."

1. INTRODUCTION

The vision of a national health information infrastructure is simple. Relevant medical information should flow seamlessly across computers, devices, organizations and locations as needed. Evidence exists that doing so can offer significant improvements to patient care and dramatic reductions in costs [2]. Desire for a national health information infrastructure dates back to 1997 [3]. For the last 12 years there has been a slowly progressing bottom-up approach to build an infrastructure by constructing independent regional data centers and exchanges [4, 5]. But with the passage of the American Recovery and Reinvestment Act of 2009 ("ARRA" or the stimulus bill) [6], the financial incentives, political will, and policy attention have all aligned to attempt to make the vision a reality by the year 2015. Initial ARRA efforts have already made resources available to support regional data centers and exchanges [7]. But a set of regional data centers and exchanges speckled across the country does not itself constitute a sufficient solution. There remains a critical gap between the bottom-up approach and achieving the promise of a national health information infrastructure quickly because questions about patient identification, record consolidation, provider connectivity, sustained participation, quality assessments, and data accountability remain unanswered. This section describes the gap and the remainder of this paper shows that the medical billing framework has the necessary features to bridge the gap.

Imagine you find yourself visiting a city in another state, and before you know what happened, you are unconscious in an emergency room. The treating physician has no knowledge of any of your current medications or allergies. If only there was a way to retrieve that information from your local pharmacy and doctor's office. It could save your

life! About 75,000 deaths may result each year from preventable medical errors [8]. So, it is easy to see why maintaining a patient's active medications and allergies list is a stated objective for the national health information infrastructure to achieve by the year 2011.

Some areas, such as Indianapolis, Indiana, organized themselves to maintain active patient medications lists for use in emergency room scenarios like the one described above [9]. Of course, the Indianapolis system only covers local patients appearing in local emergency rooms, not visitors from other states. Still, one can see how expanding the patient information beyond medications and allergies and replicating the approach to other regions of the country can constitute a bottom-up means of providing important elements for a national health information infrastructure.

Health information technology (HIT) concerns the comprehensive management of health information and its exchange between patients, providers, government, and quality entities and insurers [10].

Researchers found that in general, broad and consistent utilization of HIT will: improve health care quality, prevent medical errors, reduce health care costs, increase administrative efficiencies, and decrease paperwork [2, 11]. Interoperable HIT will improve individual patient care. Public health benefits include early detection of infectious disease outbreaks, monitoring chronic disease management, and assessing healthcare quality.

In 2009, Congress enacted ARRA, an economic stimulus package to distribute $787 billion. ARRA includes domestic spending in healthcare that total $148 billion, of which $19 billion is for HIT and the national health information infrastructure specifically. The Office of the National Coordinator (ONC) within the Department of Health and Human Services (HHS) is charged with promoting the development of the national health information infrastructure. Tasks involve identifying critical applications and important health care quality measures ("meaningful uses"), aligning economic incentives with technology features that enable meaningful uses, establishing standards of information exchange, and promoting mechanisms to protect patient privacy.

By December 2009, HHS must adopt, through the rule-making process, an initial set of standards, implementation specifications, and certification criteria for new computer systems. Eligible professionals and hospitals, who demonstrate that they are meaningful users of the national health information infrastructure, will receive financial incentives through the Medicare program to purchase these new systems, up to $15,000 for the first payment year, and reduced in subsequent years: $12,000, $8000, $4000, and $2000, after 2015.

The approach to constructing a national information infrastructure, so far, has centered on identifying meaningful features to include in new computer systems for health care providers and providing regional and statewide support to facilitate sharing patient information.

The technical distinction between a data center and a federated database usually refers to whether information is replicated (i.e., a data center) or whether a pointer and means of access is stored for retrieving the information from its originating database (i.e., a federated database) [12]. However, in public discourse and healthcare use, the term "health information exchange" (or "HIE") relates to either a data center and/or a federated database, indistinguishably [13]. The overarching services provided by an HIE is not only providing connectivity, but also resolving interoperability conflicts. An HIE makes sure the meaning of the information remains the same regardless of the originating data capture platform [14]. To do so, it is sometimes easier to maintain a copy of the received translated information. For the remainder of this writing, unless stated otherwise or is clear from context, the term "exchange" or "HIE" relates indistinguishably to the technical concepts of a data center or a federated database.

The idea of the bottom-up approach is as follows. Local health care providers and hospitals contribute patient information to regional exchanges, which in turn, enable information exchange among various entities in the exchange's region of service.

Unfortunately, new provider systems and exchanges alone are not sufficient to realize the vision of a national health information infrastructure. Many geographical areas will still not have exchanges and the amount and nature of information included in any two exchanges may differ. Quality measures require national knowledge, but supporting data may be trapped in regional silos. Even providing medications and allergies for an unconscious patient in an emergency room in another state would not be generally possible in the absence of a national scheme for identifying patient records and authenticating providers.

Many operational questions remain unanswered. How are records for the same patient identified as belonging to the same person? What information is made available to which providers? How is relevant patient information determined and consolidated and provided prior to the delivery of service? How are data audits conducted across the network? How is data provenance and integrity assured? How are corrections made, identified, and replicated? What incentives keep providers reporting and sharing information? How do providers connect to the infrastructure and how are they authenticated? How are national health quality measures assessed? Then, there are questions related to patient empowerment and privacy. All these questions are not trivially answered across a national setting by the mere existence of a network of autonomous exchanges. A single exchange may have answers to some questions specific to its exchange. Any two exchanges may have different answers if either have an answer at all. These questions are also not answered by the additional adoption of traditional standards [15], because these standards describe data flow mechanisms not what's appropriate content and process. The uncertainty exposes a critical gap in readiness to achieve a national health information infrastructure by 2015.

This gap in readiness is the natural by-product of the immediacy imposed by being included in an economic stimulus package. The funds must pump through the economy soon, so design decisions must happen quickly. Based on the nature of the bottom-up approach that was already underway, it seems likely that these questions would have eventually been addressed in the future, most likely once sufficient numbers of exchanges existed. Under ARRA, that time is now.

This paper describes a way to quickly close this gap by leveraging the national connectivity, established data flow, and financial incentive structure of the medical billing framework. The idea is to have a lightweight connective layer (an amended billing framework) operate as a backbone to provider systems and exchanges.

2. BACKGROUND

This section describes proposed meaningful uses for the national health information infrastructure and introduces the current medical billing framework. The next section, Section 3, introduces amendments to the medical billing framework for the purpose of helping to achieve meaningful uses by 2015, and even by 2011 as appropriate.

2.1 Meaningful Uses

In August 2009, the Federal HIT Policy Committee released a recommended list of objectives and measures as reimbursable uses for the national health information infrastructure ("list of meaningful uses") [16]. Later in 2009, HHS will propose regulation that will list the actual reimbursable uses of the national health information infrastructure. Until then, there will be ongoing drafts and discussions from various parts of HHS on the topic, likely coalescing around similar applications. So, in this writing, unless stated otherwise or is obvious from context, all further references to "the list of meaningful uses" or "meaningful uses" will specifically refer to the HIT Policy Committee list. This subsection further describes the list.

The term "meaningful use" recognizes that improved health care does not result solely from the adoption of technology but through the activities technology enables. Providers and hospitals are the primary sources of initial data capture in patient care, and ARRA empowers CMS to report quality measures from data made available from providers and hospitals. So, meaningful use activities describe a specific task a provider, hospital or CMS accomplishes. For system developers, the list of meaningful uses describe the features and functions that must be engineered into new systems in order for them to qualify for reimbursement under ARRA.

On the HIT Policy Committee's list are 122 distinct meaningful uses, divided into 5 areas of health policy priorities. Areas are: (i) improve quality, safety, efficiency, and reduce health disparities; (ii) engage patients and families; (iii) improve care coordination; (iv) improve population and public health; and, (v) ensure adequate privacy and security protections for personal health information.

Area	2011	2013	2015	Totals
I	36	15	7	58
II	7	12	3	22
III	6	6	3	15
IV	5	6	6	17
V	4	2	4	10
Totals	58	41	23	122

Figure 1. Number of meaningful use objectives per area and year. Source: list of meaningful uses [16]

The first area, "improve quality, safety, efficiency, and reduce health disparities," has the greatest number of goals and focuses on the patient-provider encounter. The third area, "improve care coordination," extends the focus to support the sharing of relevant information to other providers involved in the patient's direct care. The second area, "engage patients and families," establishes access and data sharing for a patient to his own patient information. Similarly, the fourth area, "improve population and public health," establishes access and data sharing for public health. Finally, the fifth area, "ensure adequate privacy and security protections for personal health information," addresses data integrity and data safety.

Figure 1 summarizes counts of meaningful uses by area and year of funding reimbursement, 2011, 2013, and 2015. Most of the required uses appear in year 2011 (58 or 48%), with 41 (or 34%) required for 2013 and 23 (or 19%) required for 2015. Area I has 58 (or 48%) meaningful uses; area II has 22 (or 18%); area III has 15 (or 12%); area IV has 17 (or 14%); and, area V has 10 (or 8%). Clearly, the bulk of all required activities reside in area I for 2011.

Not only are there more meaningful uses in area I for 2011 than in any other area and year, but these uses are also among the most operationally specific and self-contained. A few uses in other areas describe a rollout of a feature over time. An example is requiring provider and hospital systems to share patient information electronically with patient-controlled health records ("PHR"). In area II for 2011 is: "providers and hospitals must provide patients with an electronic copy of their health information (including lab results, problem list, medication lists, allergies, etc.) upon request, where 'electronic' may be provided by any number of secure electronic methods (e.g., connection to a patient health record, a patient portal, a CD, or a USB drive)." For 2013: "providers and hospitals must provide access for all patients to PHRs, populated in real-time with patient data."

On the other hand, some uses in other areas or years are vague. Here is an example in area I for year 2015: "CMS will report other efficiency measures to be decided." Some uses in other areas merely assert that providers and hospitals must adhere to the law. Here is an example in area V for year 2011: "providers and hospitals must comply with HIPAA Privacy and Security Rules." These regulations already govern these entities. Subsequent policy discourse is likely to flush out meaningful uses in these other areas and later years. For this paper, it seems prudent to focus attention on well-defined meaningful uses. These tend to appear in areas related directly to patient care (area I and area III). See Figure 2 for a listing.

	I. Improve quality, safety, efficiency, and reduce health disparities (2011 Objectives)	**(2013)**	**(2015)**
1	Use computer-based order entry for medication, laboratory, diagnostic, imaging, immunization, and referral orders.	…	…
32	CMS quality measure: % of orders so entered.		
2	Implement drug-drug, drug-allergy, drug-formulary checks.	…	…
3	Maintain and up-to-date problem list of current and active diagnoses.	…	…
4	Generate and transmit permissible prescriptions electronically.	…	…
5	Maintain active medication list.	…	…
6	Maintain active medication allergy list.	…	…
7	Record demographics: preferred language, insurance type, gender, race, ethnicity.	…	…
33	CMS quality measure: stratified reports by gender, insurance type, primary language, race, ethnicity.		
8	Record vital signs: height, weight, blood pressure; calculate and display BMI.	…	…
9	Record advance directive.	…	…
10	Record smoking status.	…	…
11	Incorporate lab-test results as structured data in patient's electronic record.	…	…
34	CMS quality measure: % lab results so incorporated.		
12	Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, and outreach.	…	…
13	Send reminders to patients (per patient preference) for preventive/follow-up care.	…	…
14	Implement one clinical decision rule relevant to specialty or high clinical priority.	…	…
15	Document a progress report electronically for each encounter.	…	…
16	Check insurance eligibility from public and private payers (where possible).	…	…
35	CMS quality measure: % patient encounters with insurance eligibility confirmed.		
17	Submit claims electronically to public and private payers.	…	…
36	CMS quality measure: % claims submitted electronically to all payers.		
18	CMS quality measure: % diabetics with A1c under control.	…	…
19	CMS quality measure: % hypertensive patients with BP under control.	…	…
20	CMS quality measure: % of patients with LDL under control.	…	…
21	CMS quality measure: % of smokers offered smoking cessation consulting.	…	…
22	CMS quality measure: % of patients with recorded BMI.	…	…
23	CMS quality measure: % eligible surgical patients who receive VTE prophylaxis.	…	…
24	CMS quality measure: use of high-risk medications in the elderly.	…	…
25	CMS quality measure: % of patients over 50 with colorectal cancer screenings.	…	…
26	CMS quality measure: ambulatory and hospital quality measures.	…	…
27	CMS quality measure: % of females over 50 receiving annual mammogram.	…	…
28	CMS quality measure: % patients at high risk for cardiac events on aspirin prophylaxis.	…	…
29	CMS quality measure: % of patients who received flu vaccine.	…	…
30	CMS quality measure: % of all medications entered as generic when generic options exist and relevant.	…	…
31	CMS quality measure: % of order for high cost imaging with specific structured indications recorded.	…	…
	II. Engage patients and families (2011 Objectives)	**(2013)**	**(2015)**
…	…	…	…
	III. Improve care coordination (2011 Objectives)	**(2013)**	**(2015)**
44	Exchange clinical information (e.g. medication list, allergy list, problem list).	…	…
47	CMS quality measure: Ability to exchange clinical information (e.g. medication list, allergy list, problem list).	…	…
45	Perform medication reconciliation at relevant encounters and each transition of care.	…	…
46	CMS quality measure: % of encounters where medication reconciliation was performed.	…	…
48	CMS quality measure: % of transitions in care where care record shared.	…	…
49	CMS quality measure: report 30-day readmission rate.	…	…
	IV. Improve population and public health (2011 Objectives)	**(2013)**	**(2015)**
…	…	…	…
	V. Ensure adequate privacy and security protections for personal health information (2011 Objectives)	**(2013)**	**(2015)**
…	…	…	…

Figure 2. Meaningful use objectives from priority area I, "Improve quality, safety, efficiency, and reduce health disparities," and priority area III, "improve care coordination," for the year 2011. All of the 36 total objectives for area I in the year 2011 are shown and listed as 1 through 31. Of these 17 objectives are for providers and hospitals to achieve and 19 are quality measures for CMS to compute. Five objectives (1, 7, 11, 16, and 17) pair provider and hospital objectives with CMS quality measures. Additionally, the 6 total objectives for area III in the year 2011 are shown. Meaningful uses for years 2013 and 2015 and for areas II, IV, and IV are not shown. Source: list of meaningful uses [16].

Figure 2 shows the 36 meaningful uses required for year 2011 in priority area I and the 6 meaningful uses required for year 2011 in priority area III. Objectives 1 through 17 and 44 and 45 describe activities for providers and hospitals. Objectives 18 through 36, as well as, 46 and 47 describe quality measures for CMS to compute from provider and hospital information.

Meaningful uses underlined in Figure 2 offer examples for further discussion. Meaningful use 17 requires providers and hospitals to submit claims electronically to public and private payers. Rather than submitting paper claims, new systems must provide electronic claims submission capability in order for the system to qualify for ARRA reimbursement. CMS will report the percentage of claims submitted electronically across all payers (36) to determine whether providers and hospitals are actually using the feature.

Meaningful uses 16 and 35 in Figure 2 also pair provider and hospital objectives to a CMS quality measure. Before servicing a patient, providers and hospitals should check the insurance eligibility of the patient (16). To determine compliance, CMS will report the percentage of patient encounters with insurance eligibility confirmed (35). Similar pairing exists for meaningful uses 1, 7, 11, 16, 17, 44 and 45.

The list of meaningful uses also includes requirements related to medication and allergy lists. Meaningful uses 5 and 6 require providers and hospitals to maintain an active medication and allergy list, and meaningful use 2 expects providers and hospitals to implement drug-drug and drug-allergy checks when writing new prescriptions. Meaningful use 44 requires providers to exchange relevant clinical information, such as medication and allergy lists, to others involved in the direct care of the patient. This includes providing an emergency room physician relevant medication and allergy information to care for a presenting patient, even if the patient resided in another state.

2.2 Medical Billing Framework

Figure 3 depicts the workflow from a single patient-provider encounter through the medical billing framework. The principal entities appear as rounded rectangles, business functions as ovals, and information flows as edges.

This paper groups participants in the medical billing framework into 3 groups: principal entities, care support entities, and billing support entities. Principal entities include patients, providers, hospitals and insurance companies. Care support entities include clinical laboratories and pharmacies. Except for hospitals, these principal and care support entities appear in Figure 3 as rounded rectangles.

From a billing workflow perspective, hospitals have the same billing workflows as providers, labs, and pharmacies combined. If Figure 3 did include hospitals, they would appear as rounded rectangles encapsulating copies of the provider, lab, and pharmacy rectangles. To improve readability of the diagram, this information was not replicated. The intent is to improve readability of the diagram, but not to exclude hospitals from consideration.

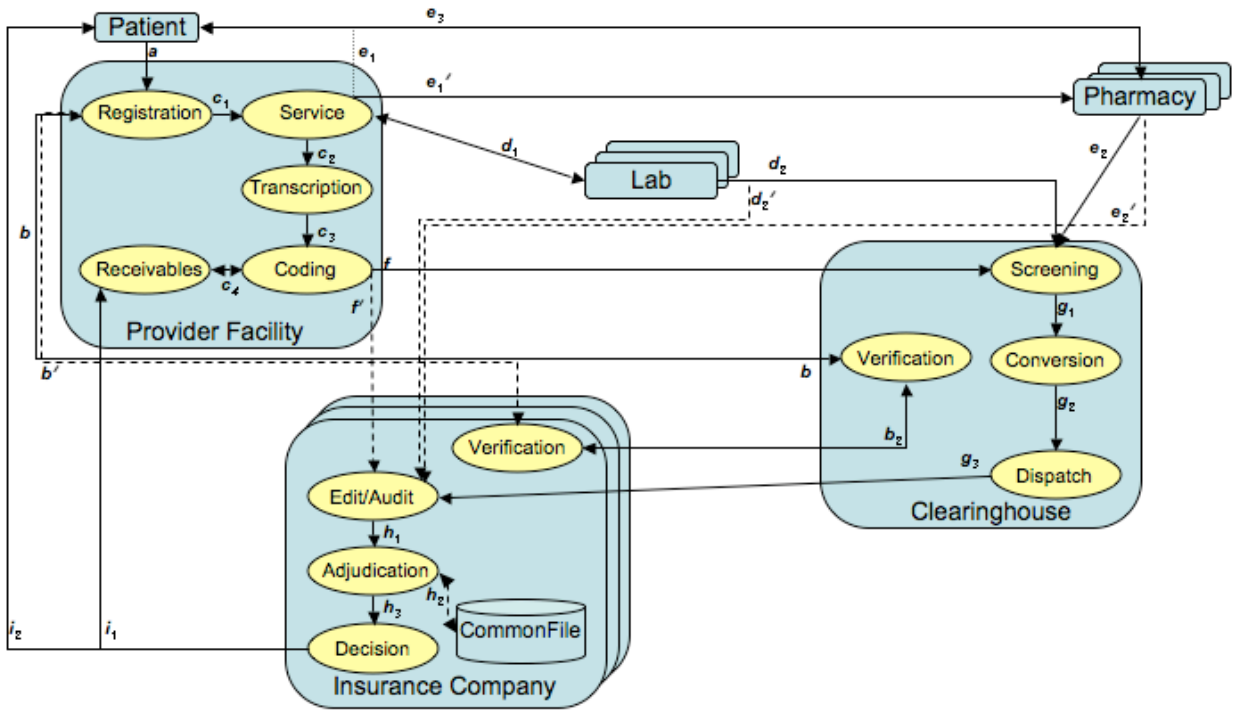

Figure 3. Current Medical Billing Framework. Depiction shows workflow for a single patient-provider encounter.

Billing support entities are outside companies that assist providers and/or insurance companies in processing claims for payment. Most (not all) oval shapes in Figure 3 describe a function done by a billing support entity. For example, consider the Provider Facility rectangle in Figure 3. A staff member usually receives the patient at the front desk (Registration), but an outside company usually does Transcription. In such cases, the transcription company is a billing support entity. The staff member is not.

Even large insurance companies use billing support entities for some of their claims processing functions. For example, Medicare is the largest payer of medical insurance claims, and is termed an "insurance company" for the purposes of this writing. Medicare processes 1.2 billion claims a year [1]. Companion Data Services, one of CMS' Enterprise Data Centers, operates the data processing systems that perform Edit/Audit functions for 65% of Medicare's claims [17] (see Figure 4 for a description of Edit/Audit).

A "clearinghouse" is a special kind of billing support entity that provides such comprehensive claims processing for a provider facility that this paper considers them principal entities (see rounded rectangle in Figure 3). To appreciate the role of a clearinghouse, consider the dynamics of medical billing. About 3 million licensed provider facilities [18] use different assortments of software to submit claims to any of 1300 different licensed insurance companies [19] in any of fifty different states. Each state has its own insurance regulatory nuances. Each insurance company has it's own internal software infrastructure for receiving claims. After submission, any errors found in a claim usually require phone calls and re-submittals until reimbursement issues are resolved and the bill is paid. Clearly, the administrative overhead to process an insurance claim for payment can be onerous for a provider facility. A clearinghouse removes much of this burden by acting as a middleman between the provider facility and insurance companies. The provider facility gains a single point of contact, the clearinghouse, and a single way to process generic claims, through the clearinghouse, regardless of the insurance company. The clearinghouse then acts on the provider's behalf, handling idiosyncrasies and complexities with the various insurance companies. Labs and pharmacies may also use clearinghouses.

Notice that a single patient-provider encounter can engage multiple labs, pharmacies, and insurance companies, but a Provider Facility tends to work with only one Clearinghouse, if at all. Multiple instances of labs, pharmacies, and insurance companies appear as stacks of rounded rectangles in Figure 3.

Most business functions (ovals in Figure 3) are easy to understand from their name and context, but others require explanation. Figure 4 provides a brief description of each entity (rounded rectangle) and business function (oval) appearing in Figure 3. The next subsection further explains the business functions of entities by walking through information flows in Figure 3.

Patient	Person receiving medical treatment
Provider Facility	Business operation of one or more healthcare professionals licensed to treat illness.
Registration	Front office collects patient's demographics and insurance information and checks patient's insurance eligibility.
Service	Medical service provided to patient.
Transcription	Transcribes dictation recorded by provider.
Coding	Claim generation, assigning diagnosis and procedure codes based on patient's illness, provider's treatment, and coding guidelines.
Receivables	Financial accounting of paid and unpaid claims at a Provider Facility.
Lab	Provides diagnostic support services to physicians.
Pharmacy	Prepares and dispenses drugs based on prescription orders from physicians.
Clearinghouse	Enables generic claim submissions from providers, insulating providers from insurance company idiosyncrasies and complexities.
Verification	Checks the insurance eligibility of the patient for the intended service.
Screening	Receives generic claims from providers and checks for errors and omissions.
Conversion	Converts each generic claim to the format required by the relevant insurance company.
Dispatch	Submits claims to insurance company as per each insurance company's guidelines.
Insurance Company	Entity that pays insurance claims, "payer".
Edit/Audit	Automated review of typos, authorization, codes, qualifications, pricing, limits, and duplications.
Adjudication	Detailed review, as needed, for irregularity, inconsistency, and disallowed entries, given policy and current and prior claims (uses a historical claims repository, **CommonFile**).
Decision	Communicates adjudication decision to provider, payment or error. Sends summary statement to patient.

Figure 4. Description of entities and business functions in the current medical billing framework. See Figure 3 for a depiction of relationships.

2.2.1. A Walk-Through the Billing Framework

The process starts when a patient, Alice, makes an appointment with a provider's office to see a provider, Dr. Bob. When Alice arrives at the facility on her initial visit, she completes forms that include her address, telephone contact information, date of birth, gender, Social Security number, employer information, insurance policy name and number, effective date of coverage, date of service, etc., and signs consent and privacy forms. On subsequent visits, Alice is asked to confirm her recorded information. This is the Registration function in Figure 3 and the flow of Alice's information is denoted as edge a.

After receipt of Alice's information, Registration continues. Dr. Bob's office contacts Alice's Insurance Company to confirm her insurance eligibility and to receive any pre-authorizations needed for service. This may be done through a clearinghouse (b then b_2) or directly to Alice's insurance company (b').

After Registration, Alice proceeds to Service (c_1). In the case of a physician office visit, Service typically involves Dr. Bob checking Alice's previous medical history, checking her, and performing procedures relevant to her current illness.

If Dr. Bob orders any lab tests, his orders go to the appropriate lab(s) over edge d_1, and the lab(s) transmit results back to Dr. Bob over d_1. A Lab submits claims to Alice's insurance company for lab services directly (d_2') or through a clearinghouse (d_2).

If Dr. Bob orders any medications for Alice, he may provide a manual or electronic prescription order. A manual order proceeds as follows: Dr. Bob gives Alice a written prescription (e_1), which she takes to the Pharmacy (e_3) and receives her medications (e_3). In contrast, an electronic order proceeds differently: Dr. Bob electronically transmits the prescription to Alice's local Pharmacy (e_1') and Alice receives the medication from the Pharmacy (e_3). If Alice's Insurance Company pays for the medication (in part or whole), then the Pharmacy submits a claim to Alice's insurance company for payment for her medications directly (e_2') or through a clearinghouse (e_2).

After Alice leaves Dr. Bob's office, his office processes paperwork for payment. If Dr. Bob dictated voice memos, his office sends his dictation along with some patient information to a Transcription service (c_2). The Transcription company sends back a written transcript of Dr. Bob's verbal notes. Dr. Bob's office then forwards Alice's file, which now includes the transcription, to a Coding service. The Coding service completes an insurance claim form with codes for diagnoses (e.g., ICD-9 codes) and procedures (e.g., CPT codes) in accordance with coding books and guidelines. Dr. Bob's office either submits the claim through a clearinghouse (f) or sends the claim directly to Alice's insurance company (f').

If a Clearinghouse is used, Dr. Bob's office submits a generic claim to the Clearinghouse, which in turn, reviews the generic claim for errors and omissions (Screening) and works with Dr. Bob's office to make any necessary corrections. Once the Clearinghouse finds no further errors, it produces a claim pursuant to the dictates of Alice's insurance company (Conversion). This may involve recoding the claim and/or reformatting its content. Then, the Clearinghouse submits the claim to Alice's insurance company based on her insurance company's submissions requirements and process (Dispatch).

Eventually, claims from labs, pharmacies, hospitals, and providers, whether submitted directly or through a clearinghouse, appear at the Insurance Company for processing. The first step involves a rigorous automated review of the claim (Edit/Audit). Edits generally test for data entry errors by checking that entries are properly formatted and fall within acceptable ranges on a field-by-field basis. System audits test a variety of conditions to determine whether or not the claim should be paid. These conditions include checks for: prior authorization, procedure codes matching diagnosis codes, a qualifying provider, a qualifying recipient, pricing, service limitations, duplicate claims, and billing code manipulation. The final step is Adjudication, which further reviews results from Edit/Audit to make a final payment decision. Finally, communication of the decision takes place (Decision). Either payment is sent to the provider (i_1), hospital, lab or pharmacy (not shown) or the reason for denial is sent. Additionally, an accounting statement is sent to Alice (i_2) denoting the total charge and any amounts for which she is responsible.

2.2.2. Billing Transaction Standards

The medical billing framework, as depicted in Figure 3, has two information circuits. The first circuit involves verifying the insurance eligibility of the patient, and is termed "Registration-Verification" in this paper, named after the business functions involved in Figure 3. The second information circuit involves submitting a claim for payment and is named Coding-Decision. Below is a description of the transactions standards used in these information circuits.

"Transactions" are electronic exchanges involving the transfer of information between two parties for specific purposes. The Health Insurance Portability & Accountability Act of 1996 (HIPAA) adopted certain standard transactions for Electronic Data Interchange of health care data. These transactions are: claims and encounter information, payment and remittance advice, claims status, eligibility, enrollment and disenrollment, referrals and authorizations, and premium payment. Under HIPAA, if a provider or hospital conducts one of the adopted transactions electronically, they must use the adopted standard. This means that they must adhere to the content and format requirements of each standard.

Here is information about the eligibility and benefit inquiry protocol, which flows on the Registration-Verification circuit in Figure 3. Prior to actually performing service and billing a patient, the provider facility may use software to check the eligibility of the patient for the intended services with the patient's insurance company. On Figure 3, see edge b' or b between Registration in the Provider Facility

rectangle and Verification in the Insurance Company or Clearinghouse rectangles, respectively. This process begins by using an electronic claims transmission standard known as X12-270 Health Care Eligibility & Benefit Inquiry transaction ("X270") [20]. A response to an eligibility request is returned by the insurance company through a direct electronic connection or more commonly a website. It is called an X12-271 Health Care Eligibility & Benefit Response transaction ("X271") [21]. Most computer systems used at provider facilities already automate this transmission.

Here is information about the claims processing protocol, which flows on the Coding-Decision circuit in Figure 3. Claim submission uses the same low-level communication standards and technologies as eligibility and benefits inquiry (above), but different transaction sets. The process begins with a transaction for a claim for services known technically as X12-837 or ANSI-837. It contains a large amount of data regarding the patient-provider interaction as well as reference information about the practice. Following that submission, the insurance company responds with an X12-997, simply acknowledging that the claim's submission was received and that it was accepted for further processing. When the claim is actually adjudicated, the insurance company will communicate the decision with an X12-835 transaction, which shows the line-items of the claim that will be paid or denied; if paid, the amount; and if denied, the reason. On Figure 3, see edge f′ or f and g_3 between Coding in the Provider Facility rectangle, Dispatch in the Clearinghouse rectangle, and Edit/Audit in the Insurance Company rectangle.

2.2.3. National Quality Reporting Through Claims

The 2006 Tax Relief and Health Care Act (TRHCA) (P.L. 109-432) required the establishment of a physician quality reporting system. So in 2007, CMS started a program that uses the medical billing framework to collect clinical measures from providers. A provider completes a claim form, by listing services and fees per line, as normal, but appends extra no cost lines that report clinical measures of the patient. When CMS receives the claim for payment, it stores the quality information and subsequently uses it to compute quality measures.

A medical insurance claim contains identifying information about the patient and the provider, patient demographics, information about the provider's practice, codes for diagnoses, and a line-by-line list of billable procedures. There is a specific code for each procedure using a standard glossary of codes. Procedure codes are usually 5 characters with an optional modifier code. For example, 99213 is the CPT procedure code for an office visit.

CMS provides a set of codes specific for reporting quality measures [22], which they term Quality Data Codes (QDCs). A QDC has the same format as a procedure code, allowing QDCs to be entered into computer billing software or written manually on printed forms in places where procedure codes would normally appear. For example, 3048F and 3078F are the QDC codes for blood pressure readings of a diabetic patient having systolic <130 mmHg and diastolic <80 mmHg, respectively.

In 2007, CMS launched the Physician Quality Reporting Initiative (PQRI) [23]. The PQRI program gives physicians a chance to earn up to a 1.5% bonus payment on all of their allowed Medicare charges if they report quality indicators (QDCs). In 2007, PQRI used 74 quality measures. That number grew to 153 quality metrics by 2009. These measures address various aspects of care, such as prevention, chronic and acute care management, procedure-related care, resource utilization, and care coordination. Most of the quality measures in the list of meaningful uses in Figure 2 already have QDCs.

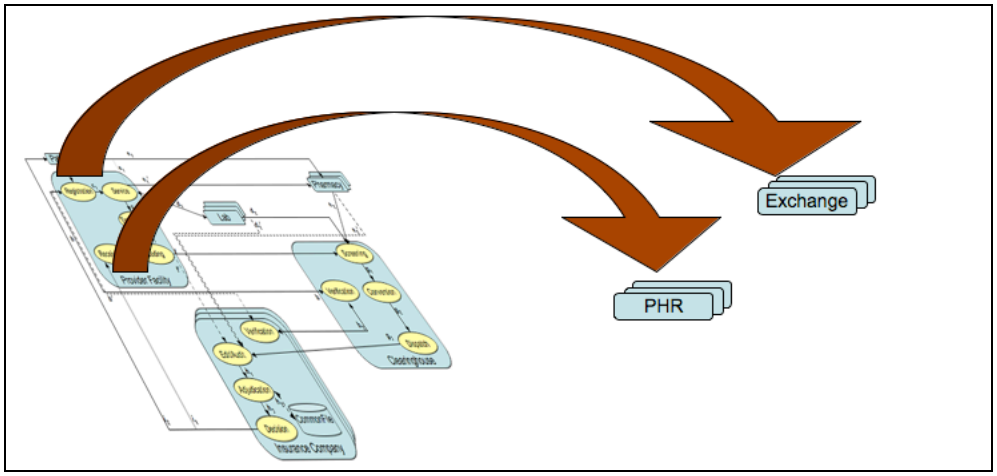

Figure 5. Patient-provider information from the Provider Facility in the medical billing framework (left) flows through alternative channels to PHRs and Exchanges (right). The large arrows denote channels of information flow that are not yet generally operational.

2.3 Other Information Flows

For completeness, this subsection examines information flows to patient-controlled health records (PHRs) and to regional exchanges in light of the previous discussion about information flows in the medical billing framework.

Meaningful uses (Section 2.1) and the bottom-up approach (Section 1) describe other flows of information from the patient-provider encounter into patient-controlled health records (PHRs) and exchanges, respectively. Figure 5 depicts these flows from the perspective of the Provider Facility discussed previously (Section 2.2 and Figure 3). These channels are different and distinct from the billing framework, and are not yet generally operational. There are two important points of contrast:

(1) Information flows to PHRs and exchanges involve different channels and are expected to include broad capture of clinical information, such as images, lab results, letters and notes, etc. This is not the same kind of lightweight information found in claims.

(2) Billing flows are already in use nationally, processing billions of claims a year. Payment is the ongoing incentive for participation. PHRs and exchanges are newer with spotty coverage. While ARRA-funded reimbursements provide initial incentive for acquisitions of systems capable of sharing data with PHRs and exchanges, there are no incentives for ongoing provider compliance.

The idea proposed in this paper is to leverage the existing connectivity and standards of the billing framework to achieve meaningful uses by sharing quality measures for CMS computation, and by providing patient information (e.g., medication and allergy lists) to the provider at the point and time of service. PHRs and exchanges will still grow and gather substantive clinical information for many other worthy uses (e.g., sharing images and lab results to avoid duplication).

3. REVISED FRAMEWORK ("BACKBONE")

Figure 6 illustrates proposed changes to the medical billing framework sufficient to enable meaningful uses for the national health information infrastructure. The basic idea is deliver relevant patient information to the provider at the point and time of care from lightweight patient information banked for the patient and to allow CMS to use banked information to compute quality measures. The modified framework ("the Backbone") introduces a new entity ("the Consortium"[1]) that facilitates the storage and retrieval of patient information with transparent controls and audits. This section describes this new entity, proposed modifications, resulting operations, and implementation details.

Lightweight clinical information gets banked with the Consortium as a by-product of claims processing. Providers and hospitals report quality measures, , allergies, and problems on claim forms along with billed services. Pharmacies report the actual medication dispensed, which might be a different or generic drug than the one prescribed. Once an insurance company adjudicates a claim, a copy of any quality measures, medications, allergies and problems found on the claim forwards to the Consortium. The whole claim need not forward. As depicted in Figure 6a, the insurance company forwards information from adjudicated claims to the Consortium on edge h_4.

Later, when a patient presents at a provider facility and the provider performs an insurance eligibility check, a consolidated copy of relevant problems, medications and allergies, forward to the provider. To accomplish this, the insurance company operates as a middleman. After internal approval of eligibility and authorization concludes, but before the response is transmitted, the insurance company requests from the Consortium a copy of the patient's clinical information as is relevant to the provider. The insurance company appends the lightweight clinical information it receives from the Consortium to the eligibility response and forwards the result.

In another version, the insurance company merely appends an access code to the eligibility response and the provider then uses the access code to retrieve the patient's information electronically from the Consortium.

Either way, a provider checks the insurance eligibility of a patient, and receives a response from the insurance company, as is done currently. If the patient is eligible for services, the response will also include direct (or indirect) access to a list of the patient's problems, medications, and allergies. Figure 6b depicts a patient presenting at a provider facility and the provider performing an insurance eligibility check. Relevant patient information from the Consortium forwards to the provider on edges b' (or b_2 and b) via the insurance company's response to the eligibility inquiry (edge k).

The following changes to the medical billing framework accomplish these activities: (1) expand content in the transaction protocols; (2) modify provider systems to submit claims that include clinical measures and to retrieve clinical information from insurance eligibility checks; (3) have insurance systems forward clinical information from claims and append clinical information to responses for eligibility checks; and, (4) setup a consortium responsible for enabling consolidation and use of, and accountable access to, acquired patient information.

Detailed discussion of these changes appears in the following 2 subsections. The next subsection (Section 3.1) examines the Consortium in detail. The subsection after that examines implementation specifics for transmitting lightweight clinical information in billing transactions (Section 3.2). The non-technical reader can advance to Section 4 for a walkthrough.

[1] An open consortium of stakeholders is necessary to guide operations on the Backbone to insure interoperability.

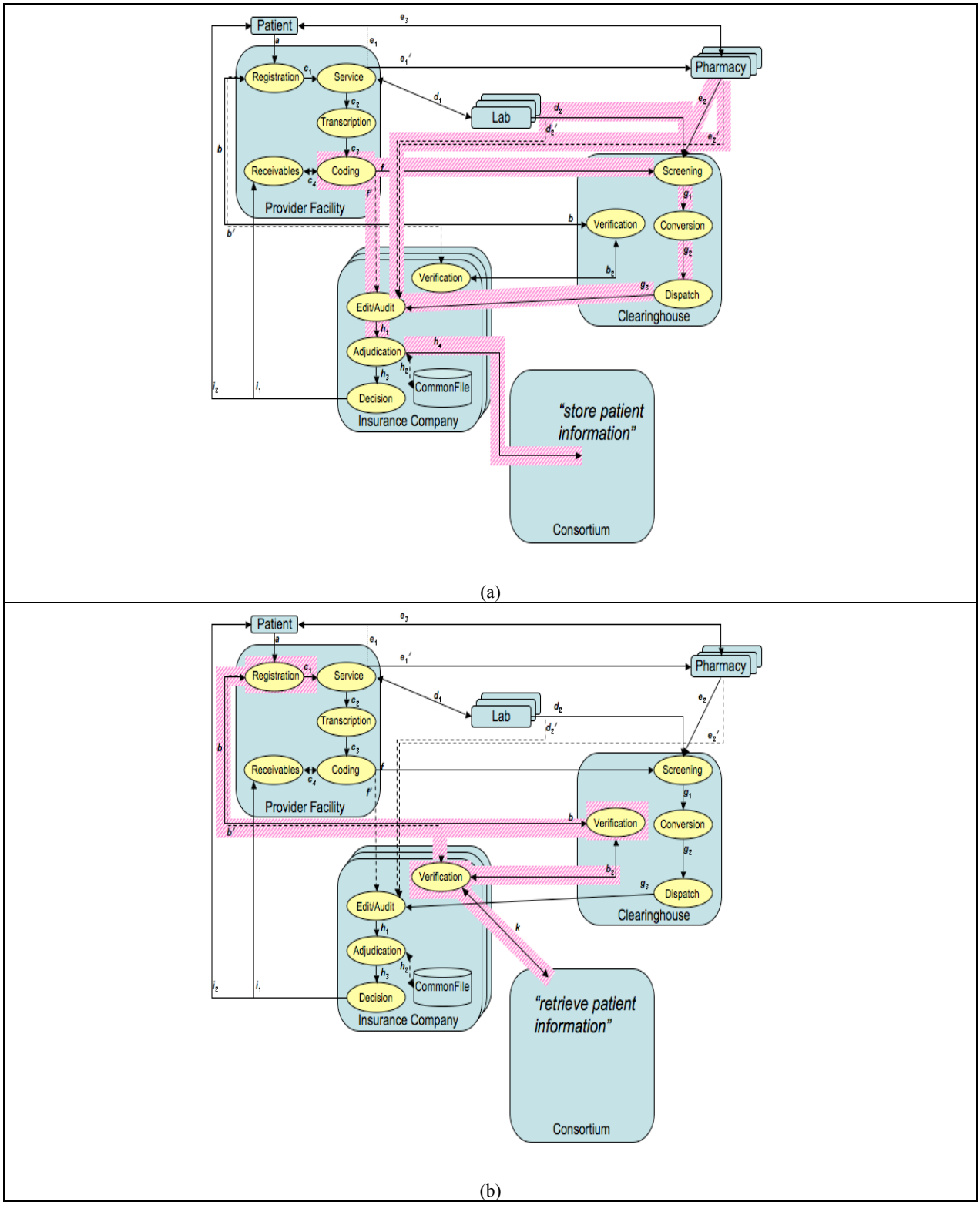

Figure 6. Primary storage and retrieval of patient information in the amended medical billing framework ("the Backbone"). Shaded area highlights modifications in data standards along (a) Coding-Decision circuit in order to bank lightweight clinical patient information and along (b) Registration-Verification circuit in order to get patient information to the provider at the point and time of service. A "Consortium" provides necessary functions.

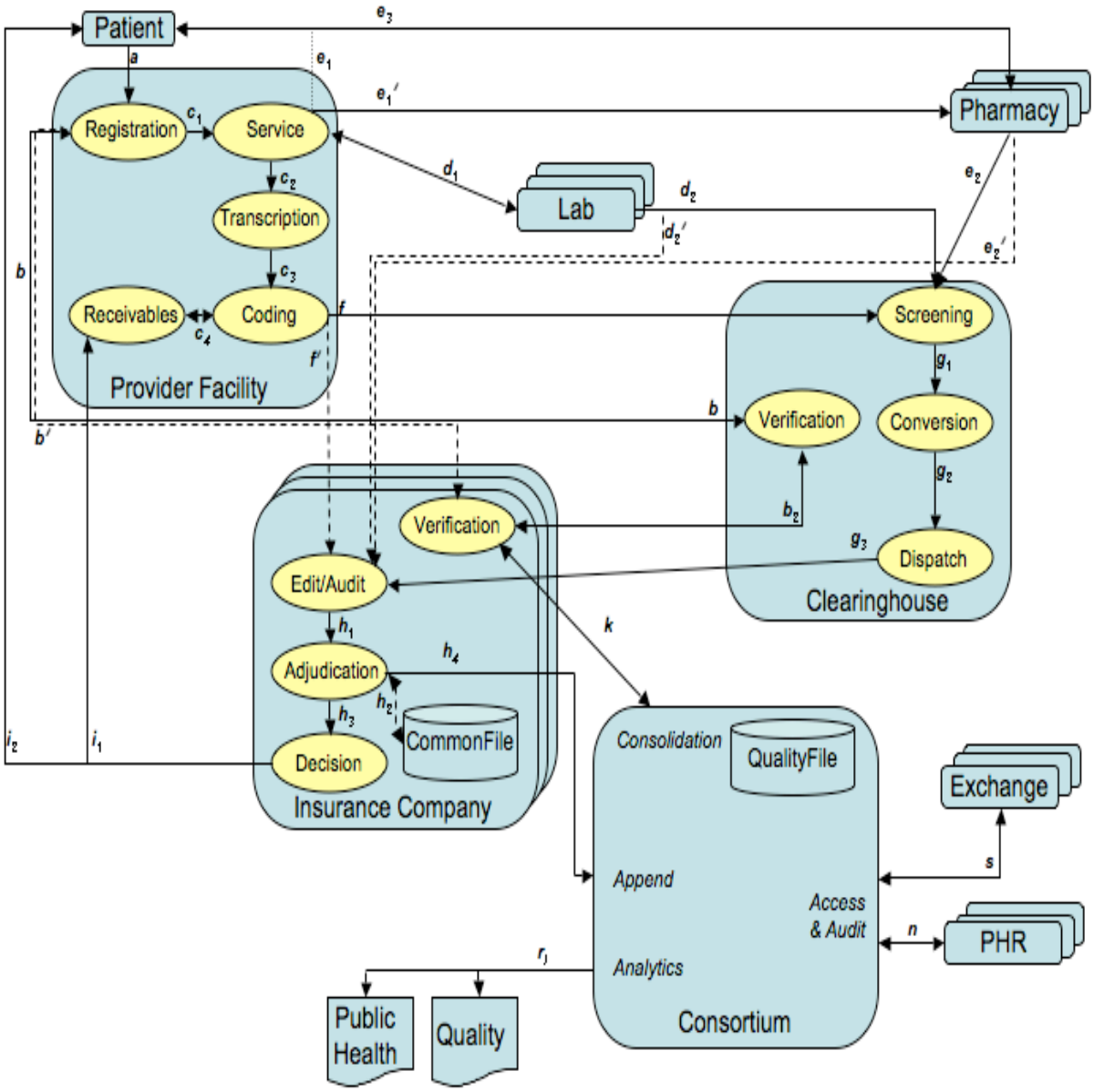

Figure 7. The amended medical billing framework ("the Backbone") showing Consortium functions, storage, and links to the medical billing framework, exchanges, PHRs, public health, and CMS (quality). The Consortium performs essential functions –namely, Consolidation, Append, Analytics, and Access & Audit. The Consortium has a primary storage mechanism –namely, QualityFile. This depiction of the Consortium identifies it functionality, external connectivity, and storage, but does not provide edges that display its workflow. See Figure 8 for two different designs of the workflow within the Consortium. Others are possible.

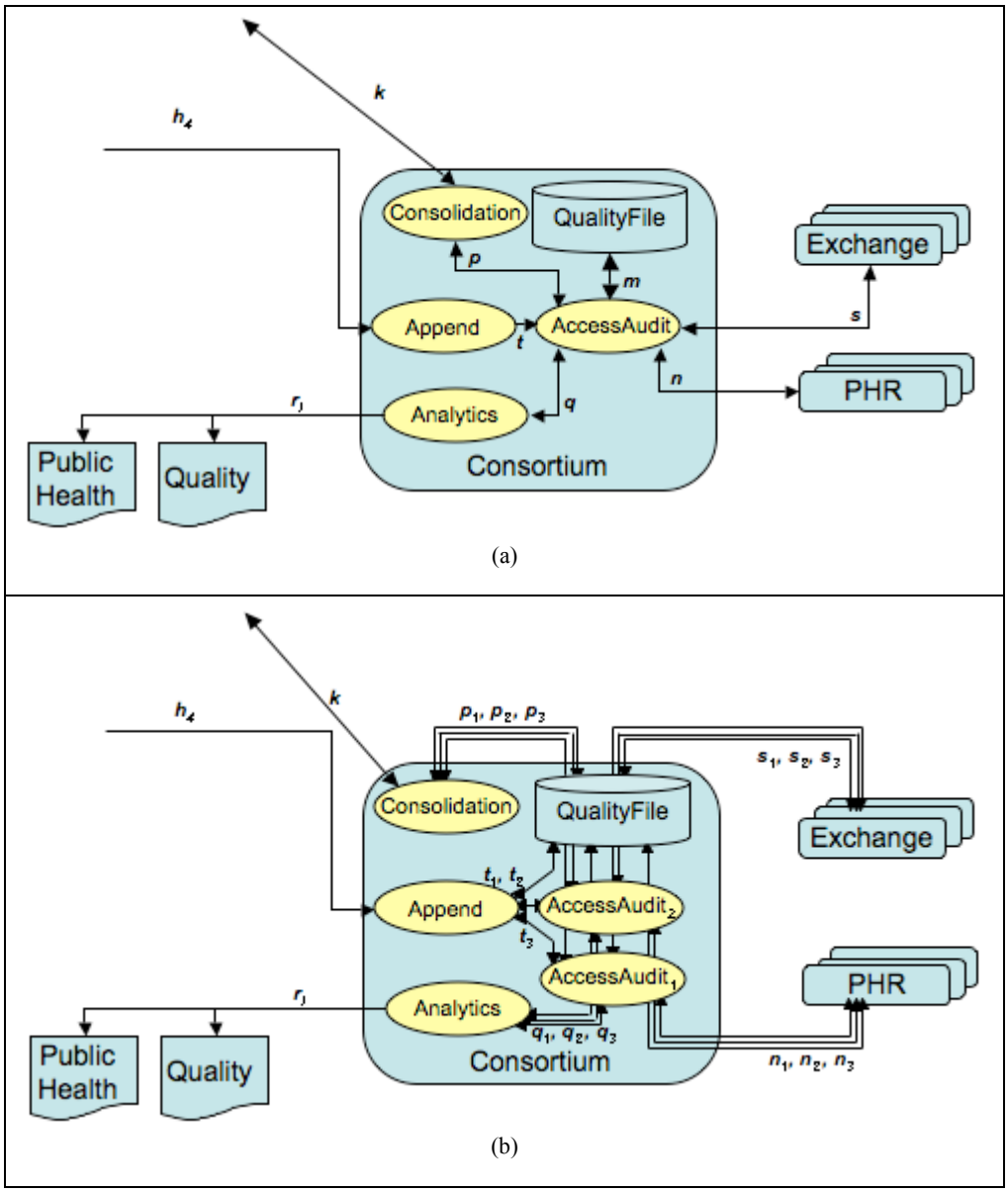

Figure 8. Two possible workflows within the Consortium. Both have de-centralized storage, but (a) has centralized control and (b) has de-centralized control. To access information in QualityFile in (a) requires the AccessAudit function only. To access information in QualityFile in (b) requires approvals from $AccessAudit_1$ and $AccessAudit_2$ separately.

3.1 Consortium Details

An open Consortium of stakeholders is the mainstay of the Backbone, orchestrating essential operations and linking the medical billing framework to other entities –exchanges, PHRs, public health, and CMS –in the national health information infrastructure. Figure 7 shows the full Backbone. The Consortium is its chief support system. It delivers critical services, encourages innovation, and grows participation by assuring sustained interoperability.

Consortium functionality is depicted in Figure 7 without revealing edges that denote workflow. There are many possible internal designs for the Consortium, and these are discussed in Section 3.1.1. Before jumping into connectivity details, it is important to first understand the overall components. Below is a description of each of the Consortium's components in terms of what it accomplishes, who performs it, and the role of the Consortium with respect to it.

"QualityFile" is the storage mechanism for the Consortium. It stores lightweight clinical information about patients. Figure 7 depicts QualityFile as a storage device, similar to the CommonFile maintained by insurance companies. A CommonFile is specific to one insurance company and contains claims information. In comparison, the QualityFile may contain information from many insurance companies and does not need to store information from the entire claim. The QualityFile may or may not be centralized. Its storage could alternatively be federated – i.e., split across multiple storage mechanisms, involving different business support entities. It can have centralized or de-centralized control. (See Section 3.1.1). The Consortium is responsible for configuration, governing polices and practices, and implementation details of the QualityFile.

"Consolidation" provides a concise, relevant representation of a patient's information. When a provider makes a request for patient information, Consolidation decides which information from what claims are relevant to the provider. If all claims were merely returned "as is," then the provider would likely experience information overload. Having providers take time to wade through outdated medications, information from prior unassociated hospitalizations, or duplicity of information captured in claims from multiple providers for the same encounter seems counterproductive. Instead, the provider should receive only the information that is timely and appropriate. Business support entities will likely perform Consolidation. The Consortium's charge is to affirm correctness of implementations, and to drive innovation through market competition. A launching step is for the Consortium to provide an initial, open source version.

"Append" is responsible for authenticating insurance companies, checking the integrity of the information provided by insurance companies, and performing operations necessary for inclusion (or exclusion) of data in QualityFile. For privacy reasons, some data may be excluded, and such decisions may be based on regulation, operating practice, or individual patient or patient-provider decision. Business associates of the insurance company are likely to implement the Append function. The Consortium establishes specifications, an interface, and an open source version.

"Analytics" and privacy-preserving analytics are responsible for scientific analysis of QualityFile's contents in order to discover and understand historical patterns with an eye towards predicting and improving healthcare service and reducing healthcare costs. Meaningful uses specifically recognize CMS as being responsible for computing quality measures and public health as receiving appropriate information, so the Analytics function provides them with necessary information.

Analytics is likely to spawn into a robust industry (with or without the Backbone), as various entities have compelling reasons to run analyses on large amounts of person-specific health data. Examples include: an analysis of drug side effects for the Federal Food and Drug administration and the detection of suspicious billing instances for fraud detection. Demand for secondary use of person-specific health data is growing, and there are many possible sources to acquire such data, including entities within the medical billing framework, exchanges, and eventually, PHRs. An extremely important advantage the Consortium offers over this unbounded data sharing environment is transparency, accountability and improved privacy protection. By providing interfaces, mechanisms for computing aggregate results, privacy-preserving tools (e.g., query restriction, anonymous linking, statistical modeling, and summary files), the Consortium should enable responsible market growth in this area –nurturing knowledge discovery in data while guaranteeing privacy protection.

"Access & Audit" is responsible for making sure that only authorized access to the QualityFile occurs and that all accesses are recorded and reported. An immutable audit may be used to provide a tamper-proof audit trail [24]. An immutable audit trail uses cryptographic techniques to record data accesses in a way that electronically resembles a continuous roll of non-erasable, non-destructible paper. Supporting business entities will likely provide innovative means of audit assessment and analysis. In terms of implementation, Access & Audit could utilize one or more access control entities, where increasing the number of entities can improve privacy and security (see Section 3.1.1). The Consortium plays a comprehensive oversight role, as it does with the QualityFile.

Beyond the Consortium's functional components described above, is the need to bridge the medical billing network to other entities in the national health information infrastructure.

The list of meaningful uses includes sharing a patient's information with the patient through a PHR and providing ways to empower the patient. The Consortium therefore establishes polices and procedures that: (1) allows a patient to get a copy of his information from the QualityFile; (2) supports patient annotation and patient or provider correction to information in the QualityFile; and, (3)

permits personal audit review so that a patient can learn who had access to what information about him in the QualityFile and when. This writing terms these kinds of patient empowerments as "fair data sharing practices" (a modernization of fair information practices [25] popularized in credit reporting) and the role of the Consortium is to establish a set of fair data sharing practices and design and implement functions in support of them.

Finally, exchanges offer a different means of storing and accessing clinical information. They are likely to hold images and more data intense information. So, the Consortium facilitates data flow across exchanges and shares QualityFile information with exchanges as appropriate.

Clearly, the Consortium plays a crucial role in the ongoing development and use of the national health information infrastructure. Its name implies an open association or coalition of stakeholders. Perhaps a public-private arrangement or a diverse industry-provider-patient coalition would work best. The goal is to have a transparent, inclusive body that can establish practices and adopt open standards related to the Consortium's functions and data storage. Sustained interoperability is a natural consequence. If successful, market competition and innovation should result. For example, society should enjoy a secure QualityFile. Providers should benefit from the best consolidation algorithm. Insurance companies should connect using the most efficient append operation. A robust analytics and privacy-preserving analytics market should emerge providing knowledge to improve healthcare service and reduce healthcare costs without sacrificing personal privacy. An individual patient should be able to exercise fair data sharing practices.

3.1.1. Consortium Workflow Options and Privacy

There are many possible designs for workflow within the Consortium, but determining which design is best depends in great part on the privacy and security goals desired. Figure 8 offers two possible workflows within the Consortium for example purposes. Most of the flows are as expected. Consolidation connects to edge k, interfacing a request for banked patient information with an eligibility check. Append connects to edge h_4, storing data from insurance companies into QualityFile. Analytics connects to r_i, performing computations on QualityFile for CMS and public health. Finally, connections to exchanges and PHRs exist through AccessAudit. In almost all designs, these connections remain the same. What tends to differ is the nature and amount of decentralization in QualityFile and AuditAccess. In general, the more decentralized QualityFile and AuditAccess, the better the privacy and security protection, but the slower the data access speed.

The simplest design is to make AuditAccess and QualityFile the same. This is centralized storage and centralized access (not shown in figure 8). A request for information is handled directly by the same entity holding all the data. Processing a request and retrieving data should be fast. But privacy concerns emerge based on who the sole entity may be and what governmental controls and transparency and accountability practices are in place. In this setting, privacy concerns rely primarily on non-technical instruments. In terms of security, a single compromise is sufficient to get identified data.

Figure 8a has decentralized storage but centralized control. Patient information is partitioned into identifying information and clinical data and each is stored separately. AccessAudit contains identifying patient, provider, and insurance company information (without clinical data). QualityFile contains dates of service, lists of problems, medications and allergies, diagnoses, procedures and quality measures (without explicit identifiers). A made-up reference number associates entries across the two collections.

Here is a quick walkthrough. A request for patient Alice's information appears at AccessAudit, which checks the identifying information it holds to locate the proper reference numbers for records about Alice, and then sends those reference numbers to QualityFile for retrieval of the clinical information.

Partitioning provides some protection from security compromises. A compromise at AccessAudit can only yield names of patients and providers, but not clinical information. Similarly, a compromise at QualityFile can yield clinical information, but with no patient or provider identities. Both would have to be compromised to get the complete information for any patient.

Figure 8b has decentralized storage and decentralized control. Append sends all claims information to QualityFile, but each value is encrypted with a distinct pair of keys. No two values, even for the same patient or claim, have the same pair of keys. Append sends identifying information about patients and providers, service dates, and a set of decryption keys to AccessAudit_1, and sends the same information to AccessAudit_2 but with the other set of keys. A made-up reference number associates entries across the collections.

Here is a quick walkthrough. A request for patient Alice's information appears at both AccessAudit_1 and AccessAudit_2, independently. Each check the identifying information it holds to locate the proper reference numbers and keys for Alice. QualityFile receives and uses the reference numbers to retrieve Alice's information. Both AccessAudit_1 and AccessAudit_2 must provide their keys to reveal the values.

Clearly, security is tighter and access is more controlled than in the earlier examples but access is much slower because each value has to be individually decrypted. A compromise at AccessAudit_1 or AccessAudit_2 can only yield names of patients and providers, but not clinical information. A compromise of QualityFile leaks no knowledge because it is just a file of encrypted values.

There are many other possible ways to orchestrate data storage and access within the Consortium. The best solution is the one that addresses specific privacy and security concerns.

3.2 Embedding Information in Transactions Standards

Getting patient information into the QualityFile is understood because CMS' PQRI (Section 2.2.3) provides a demonstrated roadmap to follow. On the other hand, retrieving patient information from the QualityFile to deliver to a provider at the time and place of service as part of an insurance eligibility check requires further consideration.

The first part –banking patient information. Figure 6a highlights the Coding-Decision circuit used to deposit lightweight clinical information from a patient-provider encounter. Providers and insurance companies currently use this circuit for submitting claims for payment. The recommended change to the Coding-Decision circuit is to include quality measures and other lightweight clinical information within the claim in exactly the same way as is done in the PQRI (Section 2.2.3).

CMS has already demonstrated success. CMS provides a set of quality codes that have the same format as procedure codes. Providers enter the quality codes as no charge line items on claims. This allows the codes to be used in billing software and transferred using the X12-837 transaction standard (Section 2.2.2). When the claims arrive for processing, CMS uses the quality codes as needed.

Here is the approach. CMS expands its set of quality codes to include all meaningful use quality measures. Pharmacy claims already include medications. Codes for problems and allergies have to use a re-coding format like CMS'. That concludes the setup. Actual use follows the CMS model. Providers enter the additional codes as no charge line items on claims and process claims as X12-837 transactions, as normal. After adjudication, insurance companies forward relevant information from the claims to the Consortium for storage.

The second part –providing patient information to the provider. Figure 6b highlights the Registration-Verification circuit used to deliver patient information to the point and time of service. This circuit is currently responsible for determining insurance eligibility. Having providers use the circuit for its originally intended purpose is itself a meaningful use (16 in Figure 2) and many systems used by providers already have this capability.

The initiating transaction, X12-270 (Section 2.2.2) remains unchanged, but changes are necessary in the response transaction, X12-271. The X270 and X271 protocol includes detailed information about the identity of the patient, the insurer, and the provider. The provider uses a code (from a list of about 125) to describe his type of service.

The format of messages sent and received is restricted and tightly controlled. Values and codes must appear in the sequence and character positions dictated by the protocol. While there are provisions for grouping requests for batch processing, there is no recurring line item and no pre-defined unused elements reserved for future use. So, there is no room in the typical exchange to include additional information as was done in the claims processing above. However, two approaches are immediately viable.

Here is the first approach. There is an X12 XML standard. Rather than transmitting the information as fixed position character strings, X12 XML changes the enveloping of the X271 transaction. An XML transmission encapsulates each value within a begin and end tag block. For example, <diagnosis> 152 </diagnosis> represents the 152 ICD-9 diagnosis code. The diagnosis tag has the following parts: <diagnosis> begins the block, </diagnosis> ends the block, and 152 is the value of tag. X12 XML encapsulates each field in X270 and X271 transactions in agreed upon nametag blocks. Inserting extra tag blocks, such as HL7 tags for medications, allergies, and problem lists [26], into an X271 transaction is seamless. The tags for medications, problems, and allergies are just added to the sequence. Computer systems that do not recognize the new tags simply ignore them, thereby making the approach backwards compatible. Further, existing applications, browsers, electronic medical records and even legacy systems support HL7 tags for clinical information. The downside is that most medical billing systems do not currently use X12 XML.

Here is the second approach. The Consortium hosts a separate electronic portal where providers can retrieve patient information with an access code embedded in an X271 response to an insurance eligibility check. While there is not enough space within X271 to transmit the actual lists of problems, medications, and allergies, there is sufficient space to embed an extra segment that passes an access code back to the provider. This would be an alphanumeric code specific to the patient and provider for the given date. The provider then uses the access code to retrieve the patient's information electronically through direct connection with the Consortium.

4. EXAMPLES

Below are two examples of using the Backbone in which having immediate access to medication and allergy lists at the time and place of service is critical to patient safety and care.

4.1 Example: Allergy

A 24-year-old woman, Eve, comes to the clinic and sees Dr. Faye for medical evaluation after her obstetrician noted a murmur on prenatal examination. Eve is in her 21st week of pregnancy and denies any symptoms. She reports no history of allergies. Physical examination showed blood pressure is 128/68 mm Hg and pulse is 89 beats per minute. Cardiac examination reveals a systolic click followed by a 2/6 late crescendo-decrescendo murmur at the apical area that diminishes with squatting and worsens with Valsalva maneuver [27].

Action without Backbone:
Dr. Faye recommends an endocarditis prophylaxis and prescribes cephalexin (Biocef, Keflex), orally, before vaginal delivery. Life-threatening complications result

because Eve did not remember, and Dr. Faye did not know, that Eve has a penicillin allergy with an immediate hypersensitivity reaction.

Action with Backbone:
The insurance eligibility check for Eve returned a penicillin allergy dated 4 years ago in another state. During physical examination, Dr. Faye asks Eve about the penicillin allergy, especially because Eve's written form has no allergies listed. Eve responded that she had forgotten about it, and went on to explain that several years prior she had been prescribed penicillin and upon ingestion experienced severe hives sufficient to present at an emergency room.

Dr. Faye recommends an endocarditis prophylaxis and prescribes Azithromycin, precluding the use of cephalosporins because of Eve's penicillin allergy with an immediate hypersensitivity reaction.

QualityFile contents for Eve:

10/27/2005[2]	Pharmacy filled prescription for penicillin.
10/28/2005	Emergency room visit: diagnosis and procedures show allergic reaction to penicillin with an immediate hypersensitivity reaction.
1/3/2009	Diagnosis of pregnancy
…	*… visits related to pregnancy*

4.2 Example: Medications

A 57-year-old man, Carl, presents at the emergency room over the holidays with chest pain (which appears to be a worsening symptom of heart failure). He had been having progressively worsening shortness of breath, weight gain, and swelling in the feet for the past two days [28]. Carl takes medications, but did not know the names of any of his medications and did not bring them with him. His physician's office and local pharmacy are closed.

Action with Backbone:
Carl's insurance eligibility check revealed that he has adult onset (type 2) diabetes. His medications revealed that Carl was taking insulin, as well as heart failure medications for the past four months. In addition, it listed that two weeks ago, a new prescription for Pioglitazone was filled (presumably to control his blood sugar).

With this medication history in hand, Dr. Dave knew immediately that Pioglitazone, like other Thiazolidinediones, can cause fluid retention when used alone or in combination with other anti-diabetic agents, including insulin. Fluid retention may lead to or exacerbate heart failure. Dr. Dave advised Carl to immediately discontinue use of Pioglitazone, adjusted his insulin dose, and added a new diabetes medication that would not exacerbate heart failure.

These examples demonstrate the critical difference in physician decision-making and patient care that can result when problem, medication and allergy lists are at the time and place of service. With Backbone, physicians were able to make efficient accurate decisions and patients had enhanced safety. These examples also underscore the urgency to save lives by having this functionality nationally available by 2011 –a realistic outcome with Backbone.

[2] The year 2005 demonstrates what's possible with Backbone over time. Data collected prior to launching the system would not necessarily be available in the system.

5. CONCLUSION

This paper makes two contributions to current discourse on the national health information infrastructure. First, it shows how to strategically leverage the medical billing framework to help achieve meaningful use objectives quickly. Second, it describes how an open consortium of stakeholders can establish and guide ongoing operations to insure interoperability.

Growing independent regional data centers, as has been the primary focus so far, leaves a critical gap in connectivity, data consolidation, national analytics, and timeliness. To close the gap, this paper proposes an amended billing framework ("the Backbone") and recommends an open consortium of stakeholders to guide ongoing Backbone operations to insure interoperability. Advantages of using Backbone are:

- Delivers patient problem, medication, and allergy lists (and can expand to include other lightweight clinical information) to the provider at the time and place of service.
- Expandable to share other lightweight clinical information to the provider at the time and place of service.
- Leverages existing national connectivity of providers and means of authentication.
- Established data flow channels, processing billions of claims a year.
- Built-in incentive (payment) for ongoing participation.
- Utilizes insurance eligibility checking, which is itself a meaningful use.
- Builds on a successful national program for computing quality measures, and this program (CMS' PQRI) uses the medical billing framework to carry clinical measures.
- Alerts providers to medication changes, generic substitutions, and patient refill history.
- Enables meaningful use objectives quickly, as early as 2011.
- Does not disrupt or change workflow for processing claims for payment.
- Interfaces with regional exchanges and personal health records.
- Nurtures innovation in analytics, privacy technology, and data consolidation and facilitates market development and growth.
- Maintains interoperability and nurtures innovation by using an open consortium to

establish practices, adopt standards, and oversee operations.

- Architects privacy protections into design decisions.
- Requires minor changes to provider systems.

A concern for any use of claims information is upcoding – the assignment of diagnosis and procedure codes to optimize income and not necessarily to be narrowly specific to the clinical condition of the patient. It seems likely that the inclusion of clinical measures and sharing reported information with patients will restrain upcoding, and possibly render it inapplicable to the uses described here.

A strategy for rolling out deployment is to start with CMS adoption. CMS could start using Backbone by 2011, and because of the large volume of Medicare and Medicaid claims, many in society would immediately enjoy national coverage, and others could follow by 2013. Of course, full deployment could start in 2011 if ONC additionally included necessary changes to billing systems as part of meaningful uses for 2011 so that new systems were eligible for reimbursement.

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REFERENCES

[1] Centers for Medicare and Medicaid Services, 2008. http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=3194 as of October 1, 2009.

[2] Chaudhry, B., Wang, J., et al., Systematic Review: Impact of Health Information Technoliogy on Quality, Efficiency, and Costs of Medical Care. *Annals of Internal Medicine*, Vol. 144, No. 10, 2006.

[3] National Committee on Vital and Health Statistics. *Assuring a Health Dimension for the National Information Infrastructure: a concept paper*. Presented to the U.S. Department of Health and Human Services Data Council. October 14, 1998. At http://www.ncvhs.hhs.gov/hii-nii.htm as of October 1, 2009.

[4] William W. Stead, MD, Brian J. Kelly, MD, and Robert M. Kolodner, MD, Achievable Steps Toward Building a National Health Information Infrastructure in the United States, *Journal of the American Informatics Association*, Vol. 12, No. 2, 2005.

[5] Glaser J., The Advent of RHIO 2.0, *Journal of Health Information Management* 21, no. 3 (2007): 7–9.

[6] American Recovery and Reinvestment Act of 2009 ("ARRA") Pub. L. 111-5.

[7] Office of the National Coordinator. *Funding Opportunity Announcement: Health Information Technology Extension Program: Regional Centers Cooperative Agreement Program*. At http://healthit.hhs.gov/portal/server.pt?open=512&objID=1335&parentname=CommunityPage&parentid=47&mode=2&in_hi_userid=11113&cached=true#3 as of October 1, 2009.

[8] Kohn, L. Corrigan, J., and Donaldson, M. (eds). *To Err is Human*. Committee on Quality of Health Care in America. Institute of Medicine. National Academy Press. 2000.

[9] Clement J. McDonald, et al, The Indiana Network For Patient Care: A Working Local Health Information Infrastructure, *Health Affairs*, 24, no. 5 (2005): 1214-1220

[10] Thompson, T. and Brailer, D. *The Decade of Health Information Technology: Delivering Consumer-Centric and Information-rich Health Care*. Office of the National Coordinator. U.S. Health and Human Services. July 21, 2004.

[11] RAND Healthcare: *Health Information Technology: Can HIT Lower Costs and Improve Quality*? At http://www.rand.org/pubs/research_briefs/RB9136/index1.html on October 1, 2009.

[12] McLeod and Heimbigner. A Federated architecture for information management. *ACM Transactions on Information Systems*, Volume 3, Issue 3. pp. 253-278, 1985.

[13] Walker J, Pan E, Johnston D, Adler-Milstein J, Bates DW, Middleton B. The value of health care information exchange and interoperability. *Health Affairs*, 2005.

[14] Nationwide Health Information Network (NHIN). U.S. Department of Health and Human Services. At http://healthit.hhs.gov/portal/server.pt?open=512&mode=2&cached=true&objID=1142 as of October 1, 2009.

[15] Health Information Technology Standards Panel. At http://www.hitsp.org/ as of October 1, 2009.

[16] Federal HIT Policy Committee, *Final Meaningful Use Objectives and Measures: 2011-2013-2015*. At <http://healthit.hhs.gov/portal/server.pt?open=18&objID=888532&parentname=CommunityPage&parentid=5&mode=2&in_hi_userid=11113&cached=true> as of October 1, 2009.

[17] Companion Data Services. Companion Data Services Awarded Additional Medicare Data Center Contract. Press Release 9/4/2009. At https://www.companiondataservices.com/News/PressReleases.aspx?ID=8 as of October 1, 2009.

[18] Centers for Medicare and Medicaid Services. *National Plan and Provider Enumeration System (NPPES)*. Database as of June 9, 2009.

[19] U.S. General Accounting Office. *Private Health Insurance: Number and Market Share of Carriers in the Small Group Health Insurance Market*. Presented to the Committee on Small Business and Entrepreneurship, United States Senate on March 25, 2002.

[20] X12-270 Health Care Eligibility & Benefit Inquiry transaction. Health Insurance Reform: Standards for Electronic Transactions 45 CFR Parts 160 and 162. *Federal Register*. Vol. 65 No. 160. August 17, 2000.

[21] X12-271 Health Care Eligibility & Benefit Response transaction. Health Insurance Reform: Standards for Electronic Transactions 45 CFR Parts 160 and 162. *Federal Register*. Vol. 65 No. 160. August 17, 2000.

[22] Centers for Medicare and Medicaid. *2009 Physician Quality Reporting Initiative Measure Specifications Manual for Claims and Registry*. At http://www.cms.hhs.gov/apps/ama/license.asp?file=/PQRI/downloads/2009PQRIQualityMeasureSpecificationsManualandReleaseNotes.zip as of October 1, 2009.

[23] Centers for Medicare and Medicaid. *Physician Quality Reporting Initiative (PQRI)*. At http://www.cms.hhs.gov/PQRI/01_Overview.asp#TopOfPage as of October 1, 2009.

[24] Lansky, D. et al. *Immutable Audit Trails*. Connecting for Health. Markle Foundation. June 2008. At https://www.policyarchive.org/bitstream/handle/10207/15494/CT3.pdf?sequence=1 as of October 1, 2009.

[25] *Fair Information Practice Principles*. Federal Trade Commission. At http://www.ftc.gov/reports/privacy3/fairinfo.shtm as of October 1, 2009.

[26] Health Level Seven (HL7). At http://www.hl7.org/about/index.cfm as of October 1, 2009.

[27] Carter, E. *Board Review Questions in Emergency Medicine. Resident and Staff Physician*. May 2005. At http://www.residentandstaff.com/issues/articles/2005-05_11.asp as of October 1, 2009.

[28] Regenstrief Institute. The Success of Just-in-Time Emergency Department Access to Patient Medication Information History. At http://www.surescripts.net/downloads/regenstrief_initiate_rxhub.pdf as of October 1, 2009.