CHAINLINK RESEARCH

Trends in Healthcare / Life Sciences and Their Impact on Electronic Commerce

By ChainLink Research

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Introduction

The US elections are behind us, the EU still stands and China and India continue to increase their production of global products for the healthcare industry. On an international and national level, healthcare is in transition. No industry, right now, in fact, is being more affected by advances in technology. But with each advance—in medical devices, medications, methods of care, and healthcare administration—new standards emerge that affect how the entities in the industry need to communicate.

With healthcare costs soaring, administrative costs comprising a whopping 7% of healthcare expenses, and increased concerns about medical errors and counterfeiting, to name a few challenges, various government agencies in the US are taking legislative action. This article will address the most recent changes impacting those who trade in the US market—across the whole value chain—and the impact the Affordable Care Act and other recent legislation will have on the deployment of standard electronic commerce communications.

Across the Chain of Care—Changing Landscape

Global and national mandates, standards, and legislation that impact the life sciences/healthcare industry are now expected to be implemented. And that includes the whole value chain from discovery through manufacturing of medical devices, supplies and pharmaceuticals; to the distributor, retailer, and the *point of care*—clinics, hospitals, physicians, and home healthcare services. These mandates have an underlying philosophy that specifically calls for integrating the *chain of care.* And this will have long-term implications for the way we transact and communicate. Therefore, they will form the foundation for now and for the digital future of the industry.

Several pieces of legislation—updates to HIPAA[1] implemented in 2012; the Food and Drug Administration Safety and Innovation Act of 2010, which mandates specific product codes on medical devices (the UDI or unique device identifier) which can support product traceability; the California SB 1307, the so-called epedigree mandate,[2] which requires digitally sharing information about pharmaceutical products across the supply chain; and of course the Patient Protection and Affordable Care Act of 2008, more easily called ACA—all play a role in our digital future.

Boiling the healthcare industry mandates down to a few big themes is not easy, but there are a few universal truisms across all the industry sectors:

- Improve care and protect the patient
- Reduce the complexity of the healthcare value chain
- Significantly increase the information available to all appropriate players, i.e., improve interoperability between systems and entities—the patient, the provider, the producer, and the supply chain—to support the most effective, timely, and efficient operation/use

"Effective use of technology and data can improve the quality of care and make our healthcare system more efficient," said Health and Human Services Secretary Kathleen Sebelius

[1] version 5010 of the HIPAA X12 EDI transaction definitions
[2] http://www.pharmacy.ca.gov/about/e_pedigree_laws.shtml

Patient safety and anti-counterfeiting issues, from a product perspective, are being driven by the FDA, which focuses primarily on consistent nomenclature and item-level data collection.[3] Organizations such as ANSI, ASC X12, HL7, GS1[4] and other industry groups have been spearheading standard product nomenclature for decades. The FDA and many state legislatures have catalyzed their adoption. Coupled with this is the broader underlying catalyst to radically streamline the digital data universe within the ACA.

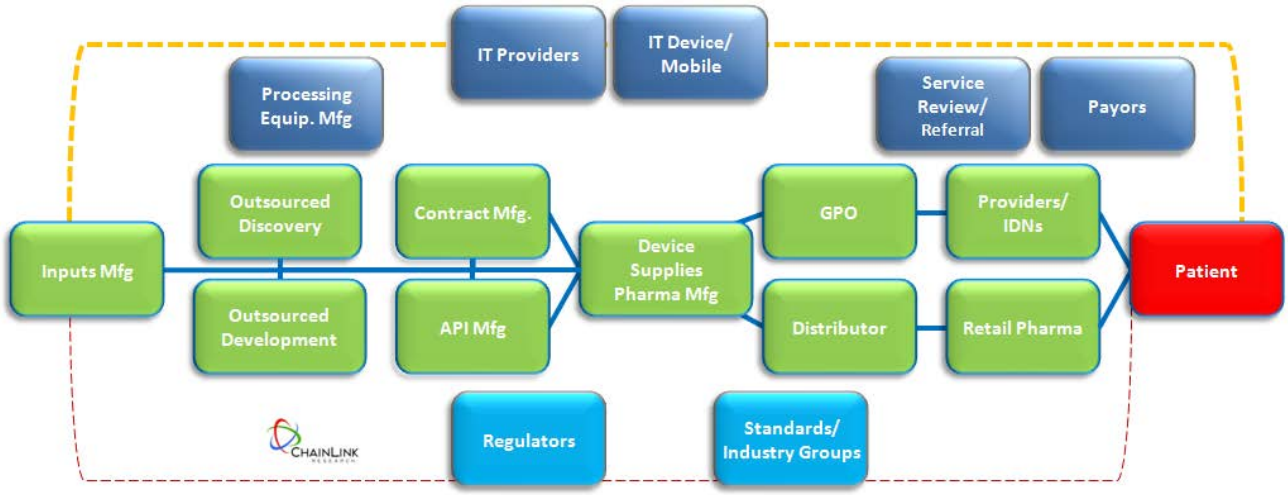

Figure 1: Entities across the Healthcare Supply Chain

EDI standards are continually adjusted by various industry groups, but they form the bedrock upon which other structures are built. And inherent within the ACA are confirmation and enforcement of these industry standards. Certainly, any providers who interact with the major players—insurance companies, hospitals, Group Purchasing Organization (GPOs) and distributors, the HHS (Medicare, Medicaid) and state Insurance will need to pay attention to and possibly amend their electronic commerce methods for products, people, and business transactions.[5]

ROI for the government and healthcare:

- More productivity/reduced errors
- Enhanced security
- Fast claims payment
- Foundation for digital applications of the future

Affordable Care Act

HIPPA and ACA have direct mandates associated with EDI. These include adherence to standards in all commercial transactions and the demonstration of quality processes to ensure accuracy in the transactions. In other words, you cannot merely use systems to automate the creation of a standard formatted transmission, but you must also document the processes used. So it is not just *that* you do it, but *how* you do it. This process approach has become a consistent requirement across all government

[3] Use of the GS1 identifier GLNs, GTINs and EPCs should be included in the EDI. Serialization programs, for example, can leverage the 856—the ASN—which provides the ability to match the physical shipment to the orders and expected serial numbers.

[4] HL7 has been more focused on patient-centered communications (patient encounter activities, prescriptions, etc.); ASC X12 focuses on financials and supply chain; and GS1 on product nomenclature. More interoperability between HL7 and x12 will come.

[5] HIPAA X12N EDI standards, as well as mandates for data encryption http://www.hhs.gov/ocr/privacy/hipaa/administrative/breachnotificationrule/brguidance.html

agencies in the last decade due to lack of adherence. Poor results are usually a result of poor methods and processes.[6]

A major philosophy underlying these mandates is the end-to-end digitizing of the value chain. Eliminating paper across the whole system should reduce errors, which reduces costs and significantly speeds up 'the system.' Delays at the point-of-care due to slow confirmation of insurance coverage, or delays in payment that place an extra burden on providers and consumers should be significantly reduced.

In addition, digital data is the foundation of the new elements of nationwide healthcare provision capabilities. Such examples are:

- Health Insurance Exchanges (HIX)—although these will be generally operated from the private sector (there often will be a public option), they will have direct state and/or federal oversight. The exchanges will become yet more entities to integrate to, and they will become catalysts for new modes of information usage—from pricing to payment. This business will be web-based, i.e., electronic.
- Health ID Card—swipeable ID card. The national healthcare ID, which allows people to seek medical care anywhere in the country, will need to conform to a variety of security and identity standards.

- Electronic Medical Record—the nationally accessible web-based patient history record. Much of the source data for this system will come from standards-based formats.
- HIPPA rules—simplification, clarity and compliant EDI transactions used by HIPAA-compliant entities. The ACA mandates adherence to these rules.[7]

Let's delve into these in a bit more detail and discuss the implications for EDI.

The HIPPA World

The ACA specifies implementation of procedures/best practices, called *operating rules*[8], which are the business rules and guidelines for the electronic exchange of information. HHS will set the pace[9] and then all *HIPAA covered entities*[10] must implement them after the 'rules' have been published.[11]

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[6] The *modus operandi* in the industry for large customers, distributors, and manufacturers is to publish their EDI standards and instruct trading partners on how they need to apply them to reduce errors and ensure seamless commerce. The challenge is that each implements EDI differently, requiring suppliers to acquire/use mapping EDI providers who will keep maps up to date.

[7] 2012 required the implementation of HIPPA 5010

[8] Section 1104 of the Patient Protection and Affordable Care Act (ACA) "…establishes new requirements for administrative transactions that will improve the utility of the existing HIPAA transactions and reduce administrative costs."

[9] The pace, we expect, will be slower than originally envisioned due to delays from the political sector. But with that in the past, the pace will pick up. (Opinion of author.)

[10] Covered entities http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/index.html Providers, or third parties who perform the services for them, can be entities.

[11] This is a 'waterfall approach': rules published by HHS must be implemented by insurers and other entities that transact across the value chain in a 'time-phased approach.' California is using a similar approach with SB 1307: first the manufacturers must comply, then the distributors, then the retailers. You can find the specifics here at http://www.cms.gov/Regulations-and-Guidance/HIPAA-Administrative-Simplification/Affordable-Care-Act/index.html

Here are the HHS publication dates—90 days thereafter, entities must follow:

January 1, 2013—Now:

- Eligibility for a health plan (EDI 270)
- Eligibility response (EDI 271)
- Health claim status (EDI 837)[12]

January 1, 2014

- Electronic funds transfers (EFT)
- Healthcare payment and remittance advice (ERA)

January 1, 2016

- Healthcare claims or equivalent encounter information (EDI 835)
- Coordination of benefits
- Health plan enrollment/disenrollment (EDI 834)
- Health plan premium payment (EDI 820)
- Referral certification and authorization transactions

These, fundamentally, put fully into practice the EDI/HIPAA required transactions and the quality assurance processes associated with them, so that errors within the systems are reduced.[13]

The Health Insurance Exchanges—HIX

In January 2014 the HIXs are due to be in place. Loaded with personal and business data, these entities will have to address highly secure and standards-based data challenges. There are various payment options and, therefore, integration between entities must occur. Standards for such activities as eligibility, electronic funds transfer (EFT) and insurance premium payments are a minimum. Expect many announcements about these throughout 2013 as plans are firmed up state by state.

Private Insurers and Healthcare Service Review, Authorization and Referral Entity

An additional note on today's healthcare system is that entities providing a healthcare services review before treatment use mostly digital services between the providers, payors, and the patient. These organizations need the EDI 278 (a Q and an R- Query and Response). This document houses more information about the patient and the proposed treatment. This transaction set can accompany other documents and has a big future in the digital healthcare universe of the future such as in Electronic Medical Records and mobile healthcare.

[12] Associated EDI notifications can be the EDI 2716 for status of a claim review and the 277 status reply

[13] HIPAA and ACA stipulate the exact format for each transaction record. Electronic transactions such as healthcare claims, claims status and remittance advices (RA), eligibility verifications and responses, referrals and authorizations, and coordination of benefits (COB), among others, are included in the rule. Its intent is to reduce the hundreds of healthcare data formats to just one that is universally implemented throughout the healthcare industry. The objective is to greatly increase the portability and accessibility of this information and decrease the administrative overhead associated with the management of the process.

Electronic Medical Record

Here is an area in which EDI does and will continue to play a vital role as various subscribers (the providers) to these systems need to integrate among themselves. In addition, these systems must be easy for the patient to understand. In order to have a national system, all providers have to subscribe to the standards. We are counting on this system to ensure immediate and accurate care as well as follow-up/ongoing care and dialogue between patients and the complex healthcare industry, i.e., all entities that are involved in their care.

Claims Administration

There are many studies that point to billions in savings due to automation and improved data accuracy in the administration of claims—between providers, payors as well as the third parties who enable the claims and payment process. EDI usage and the underlying HL7 data standards need to be addressed.

The Provider Perspective

Providers have EDI woven throughout their operation from claims management to supply chain and purchasing. These processes need to be seamless in order to ensure rapid and effective patient care, as well as ACA compliance. Even today, paperwork, follow-up, and errors slow the process and that can be painful for both patients and the provider. As a consequence of noncompliance (beyond rejected payment), providers can find their certifications withdrawn or find themselves audited due to a pattern of errors.[14]

Our future world includes automation for even the smallest providers. Many of these will seek third parties—managed-service technology providers—to ensure their compliance. In the short run this will no doubt be an added cost, but over the long run it will be a huge labor-saving benefit, as well as allowing the provider to be connected to the broader healthcare digital universe.

The Manufacturing/Distribution Perspective

Data across the supply chain has always been the long-sought-after goal for most industries, but out of reach for the healthcare value chain. Now the various trace and import regulations, the general move to quality, and the anti-counterfeiting and cold chain efforts are starting to move us there. Although those efforts often leverage other technologies to fulfill their objectives, they still rely on EDI transaction data such as the 832 product catalogue, 850 purchase orders/997 acknowledgement, 810 invoices, and the workhorse—ASN 856. Distributors also rely on the 844/849 to acknowledge the movement of physical goods.

[14] These are often designed to uncover and eliminate medical fraud, so this is not a label a provider would like to be tagged with!

Auto-ID Meets EDI—Serialization in Pharmaceuticals

Today's trading partner-compliant EDI systems house the current compliance format for labels—barcode and RFID. The so-called GTN (serialized product code) and GLN (location code, which changes as the product moves through the supply chain) should be maintained in the EDI transaction.

The application of specific compliance maps and formats for the supply chain is absolutely crucial and should be part of any system to ensure a high-integrity and high-velocity supply chain. EDI and its auto-ID partners—barcodes and RFID—must work together to ensure authenticity and security. As the physical product moves through the supply chain, it can be scanned and validated against the digital transaction—the EDI message.[15]

UDI in Medical Devices

The FDA's mandate schedule for the Unique Device Identifier (UDI) is due to be implemented by May 2013. UDI is a unique numeric or alphanumeric code unique to each device. The coding scheme was designed to mesh, as much as possible, with existing electronic standards and labeling. Coding includes the product's hierarchy: product family, device model, and the unique serial number for the actual product emerging from production. This code then needs the current production information (lot or batch number) and the expiration date. Many production and operating systems as well as EDI transactions and barcode labels already create or use this information. But now, manufacturers have to ensure completeness and consistency in using them. Many manufacturers have just not gotten around to syncing up these systems. (So now would be a good time to begin.) Again, the goal is a seamless supply chain and although the FDA's goal is patient safety, this has obvious benefits for members of the value chain.

Across the Compliant Chain

Data timeliness and accuracy are only increasing in importance, and the starting point to bigger goals is compliance. Today, all types of supply chain applications depend on integration to the EDI messages from order management to the warehouse, transportation scheduling, inbound processing, etc.

Distributors are expected to have advanced capabilities to provide rapid ordering and inventory status. Now with many of the new labeling standards, distributors will need to be in sync with the new serial number and UDI data, processes, and labeling from the manufacturing and/or packing lines. Serial number tracking, adding location data to labels and records, auditability and reporting are all capabilities expected by upstream and downstream partners. That, in turn, becomes the gateway to greater business value.

[15] Any technology or managed service used should have the ability to provide both EDI and barcode symmetry to ensure accuracy of business systems, scanning, and data security.

One of the holy grails of end-to-end EDI is gaining access to retail and hospital inventories to understand demand and provide improved inventory positioning. This cannot occur without updating the location codes (GLN) in the EDI transaction. The push for GTN and GLN adoption across the chain, all the way to retail, is an ongoing effort in industry groups. And certain retail pharmacies and hospitals have made significant progress here sharing product movement and point-of-sale data with their suppliers.

Peering into the future, manufacturers would like to benefit from the better 'outcome data' that is part of the ACA objective so they can understand the efficacy of their products and the shifting demand patterns as alternative treatments and protocols are recommended.

Conclusions—Technology Stepping Stones

Regardless of the mandates, applying standards-based business approaches between trading partners ultimately streamlines your supply chain and reduces administrative costs. Today, the life sciences/healthcare supply chain is fundamentally disjointed, though standards do exist. The hospital enterprise systems are a collection of poorly integrated solutions. And the supply-side is going through transition as companies have mergers, complex research and outsourced structures, and internal organizational challenges. Though there are many efforts to provide more broad-based solutions which can provide powerful payback in terms of cost reduction, it will be disruptive and challenging to get there.

Supply chain compliance is absolutely foundational to technological advancements which require accurate data at each step in the value chain. Without compliant data, the use cases discussed will be ineffective and the goal of reduced costs in the chain, better safety due to correct dispensing of medications, and mobile applications for providers and patients won't be achieved. The underlying data structures have to be standardized and have to be fully deployed so that data is accessible and accurate at each stage across the chain of care.

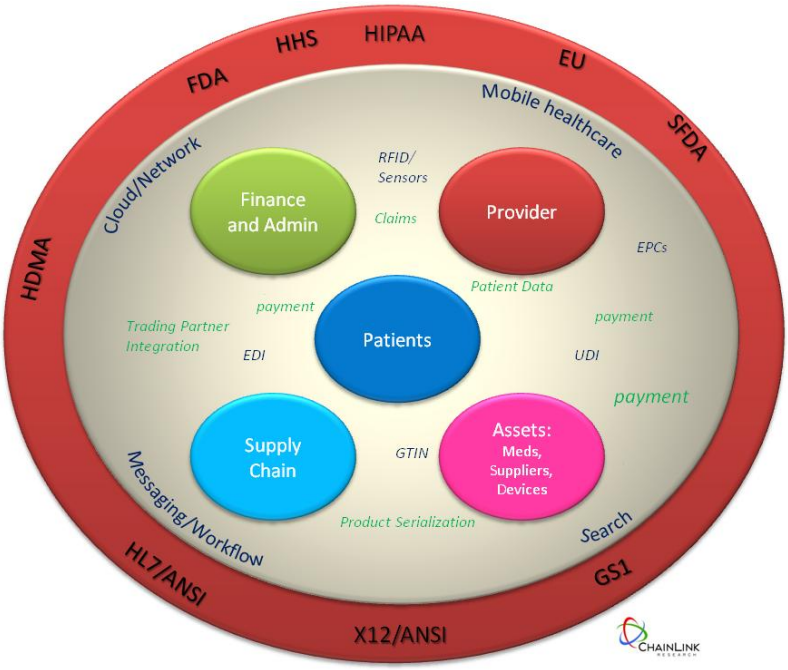

Figure 2: ***The World of Standard Life Science/Healthcare Data***

At first blush, the tidal wave of mandates seems overwhelming and costly. But many organizations have been on the journey to, or already have, strong trading partner systems. So those organizations should look to leveraging a richer source of information, as a more reliable, timely, and complete source of information emerges for planning and operations.

Larger enterprises that have created portals for supplier compliance can extend and support standards adoption through their supply chain and are already reaping the benefits. This approach *is not out of reach for smaller firms*.[16] Using a managed service provider to do this for you and your suppliers is an alternative for mid-size firms. Alternatively, managed EDI services do exist to support the required adoption. Using an EDI provider who already has experience in supply chain with distributors and hospitals as well as the provider/claim side can ensure that adherence to mandates is more simply achieved.

Organizations that have less technological prowess must confront some realities. The health industry and its supply chains—pharmaceutical and medical device sectors—thrive on technological innovation across the value chain. So part of the corporate goal now must be embracing technology skills. Used wisely, technologies, starting with the basics like EDI, can elevate performance in significant ways. And adherence will be needed just to meet the mandates.

Inherent in all the government mandates is a blend of prescriptive 'must comply' and funding catalysts to fulfill a future vision of a harmonized healthcare system. We can look to a future of nationwide information to ensure cost-effective administration of the healthcare system.

[16] Read *B2B Integration—Making Technology Decisions that Scale With Your Business*

References:

Centers for Medicare and Medicaid Services (information on the operating rules for ACA): http://www.cms.gov/Regulations-and-Guidance/HIPAA-Administrative-Simplification/Affordable-Care-Act/index.html

FDA site for Unique Device Identifier (UDI): http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/default.htm

GS1— information source for item-level data standards: http://www.gs1.org/

HDMA (Healthcare Distribution Management Association): http://www.healthcaredistribution.org/

Guidelines for implementing various EDI standards for supply chain from ordering to billing in the distribution chain: http://www.healthcaredistribution.org/resources/currentpubs.asp

HL7 (Health Level Seven): was founded in 1987 to produce a standard for hospital information systems. HL7 International was accredited in 1994 by the American National Standards Institute (ANSI) http://www.hl7.org/implement/standards/index.cfm?ref=nav

Administration standards across healthcare entities for administrative communication, transactions, product labeling standards, etc.: http://www.hl7.org/implement/standards/product_section.cfm?section=3

HL7 Implementation guidelines for documents: http://www.hl7.org/implement/standards/product_section.cfm?section=5

Good sources of information for understanding interoperability standards about *Meaningful Use* and the *Electronic Medical Record:*

HIPPA: http://www.cms.gov/Regulations-and-Guidance/HIPAA-Administrative-Simplification/HIPAAGenInfo/index.html?redirect=/HIPAAGenInfo/

HHS: Privacy Mandates dictated by the US under Health and Human Services (HHS) http://www.hhs.gov/ocr/privacy/hipaa/understanding/index.html

ASC X12: http://www.x12.org/

Site for the **ACA** (Affordable Care Act): http://www.gpo.gov/fdsys/pkg/BILLS-111hr3590enr/pdf/BILLS-111hr3590enr.pdf

Report: B2B Integration: Making Technology Decisions that Scale with Your Business: EDI technology investment strategies for small to mid-size business.

719 Washington St., Suite 144

Newton, MA 02458

617-762-4040

Email: info@CLResearch.com

Web: www.ChainLinkResearch.com