



Medical Device Supply Chain Council

UDI Standards Adoption Network

September 30, 2010



Market Drivers for Global Data Standards

- Many markets/countries already require the use of GS1 or other data standards in the supply chain,
- FDA's Unique Device Identifier (UDI) pending regulations will require either the GS1 or HIBCC standard,
- U.S. Healthcare Industry "GLN and GTIN Sunrise Dates," and spilling over to other top markets, and
- Many other regulators already require GS1 standards (think healthcare reform)
- *There are two known standards development organizations:
-GS1 and HIBCC*
- *However, there are many standards advocacy organizations.*
- *GHX is neither, we remain open and neutral, and member-driven.*

Global Data Standardization at GHX

In the last year,

- GHX Health ConneXion, a certified data pool – live since April 2009
- On the GDSN Board
- Engaged with GS1 US, Canada, UK, Australia, & Germany member organizations
- On GS1 US Healthcare Leadership Team
- Participate in the GS1 Global Healthcare Work Groups,
- Initiated the *GHX Industry Standards User Group* in June 2009
 - Over 161 GHX members & growing – monthly web/conference meeting
- Current GLN pilots, implementation guides, and white papers – updating collaterals Q310
- Coming Soon:
 - **GHX Health ConneXion User Group – to drive the healthcare data pool**

And,

- GS1 Standards, work with members for implementation support
 - New GLN Tiered Services for Providers and Supplier – Q310, continue pilot work
- HIBCC – continue to work with members' request
- Classification – UNSPSC and eClass, plus other content-related services
- USA's FDA Unique Device Identifiers (UDI) Initiatives
 - Completed FDA UDI pilot with buyers and sellers Q309
 - In total, executed on 4 phases of work for the UDI initiatives



GHX Health ConneXion™

a GDSN-certified data pool



GHX Health ConneXion™

- Increased Activity
 - 2 Live Suppliers in last 30 days
 - 2 Live Recipients in last 30 days
 - Siemens Published US Catalog
 - Suppliers publishing to large distributor
 - Additional GPO
- Expanding Global Focus
 - Australia
 - Germany
 - United Kingdom
 - Canada
 - Netherlands
- Regulatory – GDSN, pending regulations, provides one way in which to publish to the pending UDI Database/System

**GHX Health ConneXion™ is a
GDSN Certified Data Pool**

**GHX Health ConneXion™
Services include:**

**Data Pool AND On Boarding
services**

**Integration Options include
XML, 832, Flat File via FTP, AS2**

**Single Data feed to GHX allows
Suppliers to publish to GDSN,
AllSource™ and to pending UDI
system.**

A portion of members either live, or in process:

Baxter
BD
C. R. Bard
Dekroft-Metz
JJHCS
Owens & Minor
Orlando Health
Novation
HPG
Sisters of Mercy
Teleflex
Abbott
University of Kentucky Hospital
Aurora Health
Siemens
Ohio State University Medical Center
W.L. Gore
Aurora Healthcare
...plus more

***this is GDSN Growth
....specific to Healthcare***

Committed to GHX before 2012:

BBraun
Hospira
Edwards
Covidien
....plus more



GLNs at GHX Transactional & Reconciliation

A Two-Pronged Approach



GHX Customer Cleanse – Reconciliation Approach

- Service is currently available
 - Delivered to multiple clients
 - Inquiries number over 200
 - Seeing an increase in interest and activity over last 30 days
- Reasons for engagement vary
 - 2010 GLN Sunrise is primary
 - Internal Sales & Marketing needs
 - Pending UDI regulation – encouraging all standards

US Market “Pulse” – Transactional Approach

- “Transaction” interest has declined in volume over the last 3 months at GHX
- Expect increase in inquiries for October/November
- Customer Impediments
 - GLN Standard education
 - MMIS Technology requirements
 - Upgrade timelines and expense
- Many unknowns for more complex Trading Partners
 - Just In Time (JIT)
 - Low Unit of Measure (LUM)
 - Class of Trade specifics
- Long Term Strategy development and approach is required for cost effective adoption



GHX Health ConneXion™

Andy Martin
Sr. Product Manager



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- Regulatory – anticipated that GDSN data pools will be another conduit to publish data to UDI

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and to AllSource™ (UDI in the
future)**

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***GDSN Growth
....in Healthcare***

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GHX and UDI Efforts



GHX & the FDA's UDI Initiative

GHX has worked with FDA to:

- Ensures cross-functional industry forums for FDA for UDI requirements, when requested,
- Provide our industry's expertise as aligned with publishing and subscription product data in healthcare US landscape,
- Align with GS1 adoption per our member's focus,
- Prepare GHX Health ConneXion™ data pool, to communicate for UDI preparation,
- Engage with European Commission, and other non US UDI alignment and GHTF ,
- Sept 2009, completed the UDI pilot with FDA, and
- Continues to engage with FDA and members of supply chain to prepare for the UDI system.

FDA's UDI Database Pilot Report

From: U.S. Food & Drug Administration (FDA)
<fda@service.govdelivery.com>

Date: Wed, 25 Nov 2009 07:55:42 -0600 (CST)

Subject: Unique Device Identification Update

FDA recently completed a pilot test of a prototype UDI Database (UDID). The purpose of the pilot was to better understand the data attributes and assess the feasibility and usability of the UDID. We were especially interested in manufacturer's ability to identify and organize the data and load it into the database as well as user's ability to use, retrieve and export the information.

The report is available at:

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentifiers/ucm191770.htm>

Questions

**UDI Conference - Dec 1 & 2
Baltimore, MD**

GHX Industry Standards User Group - Dec 3



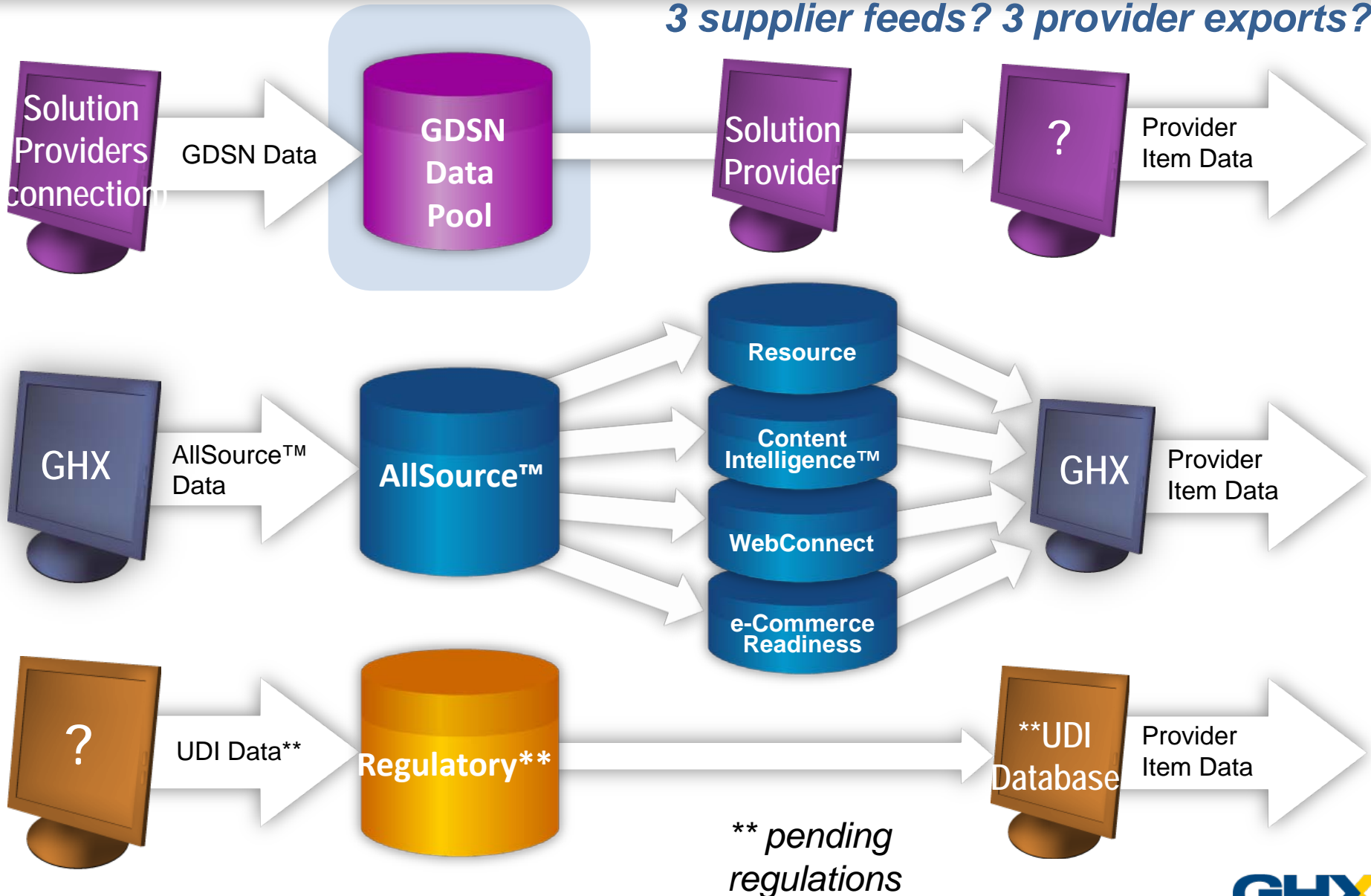
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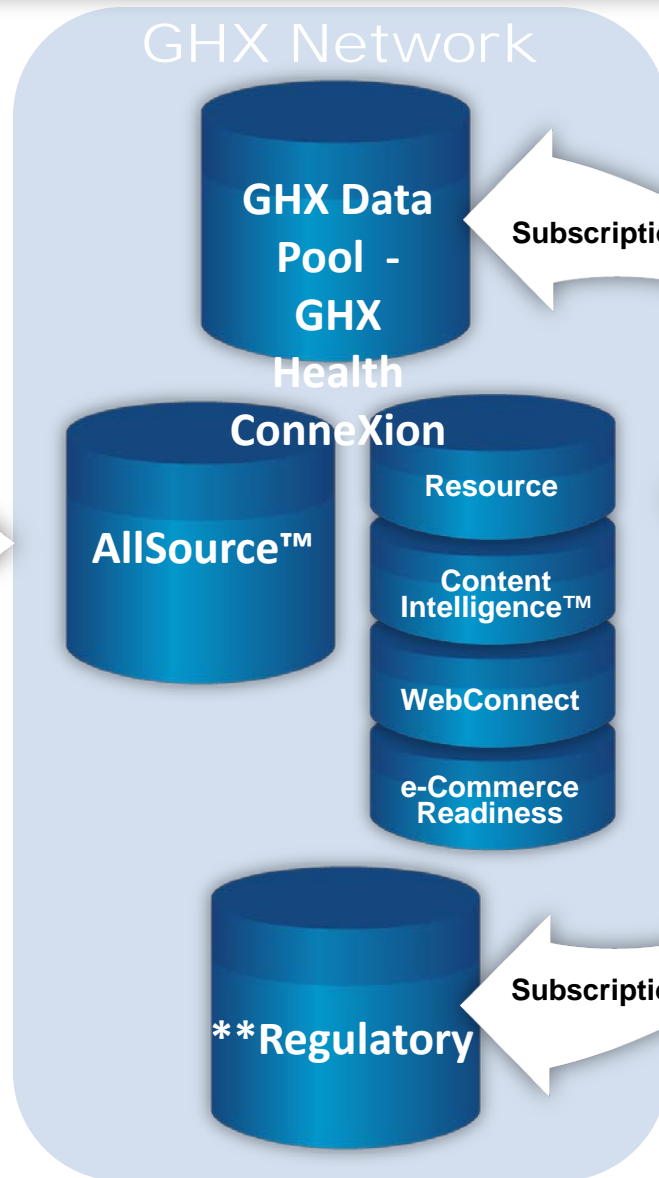
USA mobile +1 -303-961-7050

Pending Data Challenges

3 supplier feeds? 3 provider exports?



GHX Consolidated Solution to the Challenge



GDSN (+UDI) & Non-GDSN Data

Supply Side

- Goal is to create a common Non GDSN Message
- Message contains
 - **Regulatory & AllSource™ data
- Allows suppliers to leverage the single pipe into GHX, for all forms of needed product data!



Provider & Data Consumer

Buy Side

- GHX becomes a provider portal or single stop for:
- GDSN Subscriptions
 - UDI Data **
 - NuVia & Virtual Item Master

** pending regulations

