



Using Health Industry Number (HIN) Tools for 340B and DSCSA Requirements





The Health Industry Number (HIN®) System

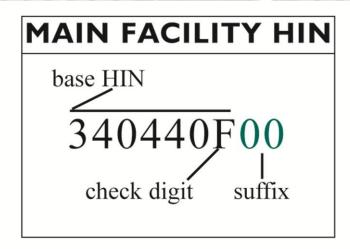


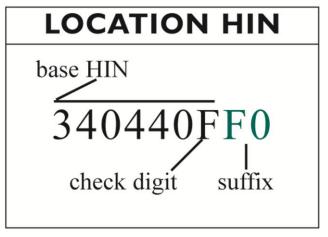
- The Health Industry Number (HIN) is a unique, universally accepted standard identifier
- It identifies the customer's location and class of trade
- The HIN is extremely flexible; Not only can it identify specific health care facilities, but also specific locations and/or departments within them



How is the HIN Structured?

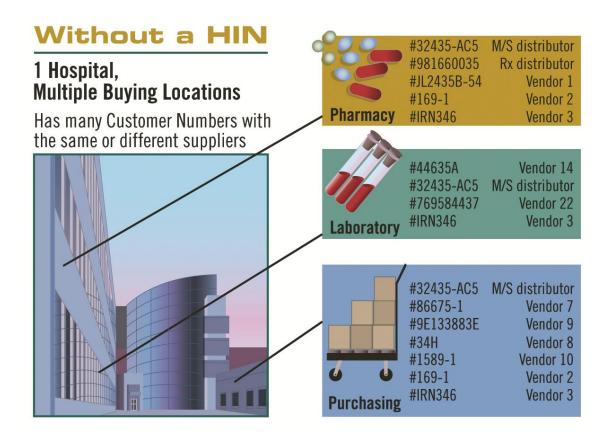
- Base HIN identifies a health care entity at a particular location
- Check digit
- The suffix identifies the particular services or activities within a health care entity

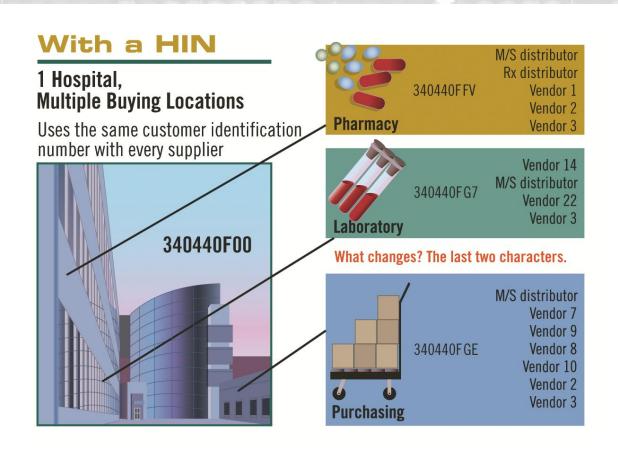






How is HIN Used?







How is HIN Used?

- Facilitation of chargeback processing by pharmaceutical trading partners
- Validation of pricing when manufacturers receive chargeback requests from distributors



How is the HIN data maintained?

- The HIN database is licensee driven; the data originates from the information submitted by authorized HIN licensees
- The data is validated and verified by HIBCC
- Licensees are typically manufacturers, distributors,
 wholesalers and group purchasing organizations (GPO)



- HIBCC was founded in 1983 by healthcare associations focusing on developing safer standards for the healthcare industry.
- •HIBCC is an international standards development organization accredited by the American National Standards Institute (ANSI).
- HIBCC is accredited by the U.S. FDA and the European Commission as an issuing agency for their respective Unique Device Identification (UDI) regulations.



Using the HIN[®] System for 340B PHS Drug Pricing Program



HIN and 340B Program

Distributor Accounts

Sample Hospital

GPO Inpatient Account

Main Pharmacy
22 Hospital Road

Non-GPO /WAC Outpatient Account

Main Pharmacy
22 Hospital Road

340B Outpatient Account

Main Pharmacy
22 Hospital Road



HIN and 340B Program

Distributor Accounts

Sample Claim	
Customer Name	Sample Hospital
Customer Number	123456789
Customer Address	22 Hospital Road
HIN	2E84L69F3
Product Number	XXXXX-XXXX-XX
Quantity	10
Contract Type	WAC
Chargeback Requested	\$50.00
Product Cost	\$250.00
Contract Price	\$300.00

GPO Inpatient Account

2E84L69F2

Non-GPO /WAC
Outpatient Account

2E84L69F3

340B Outpatient Account

2E84L69F4



HIN and 340B Program





Using the HIN® System for DSCSA Requirements



What is the DSCSA?

- Drug Quality and Security Act (DQSA) was enacted by Congress on November 27, 2013.
- The Drug Supply Chain Security Act (DSCSA) as outlined in Title II of DQSA will enhance the FDA's ability to help protect the consumers from exposure to drugs that may be counterfeit, stolen, contaminated, or otherwise harmful.



DSCSA Section 582 Requirements

To whom does this section apply?

Manufacturers

Wholesale Distributors

Dispensers

Repackagers

Before or upon transfer of product ownership, provide:

- Transaction history
- Transaction information
- Transaction statement

For the complete guidance, refer to Title II of DQSA, Drug Supply Chain Security Act, Section 582 Requirements



Transaction Information includes:

Product Information

Date of transaction

Date of shipment, if more than 24 hours after the date of transaction

Business name and address from whom ownership is being transferred

Business name and address to whom ownership is being transferred

856 Advanced Ship Notice (ASN)

The HIN is used as an organizational identifier to identify the seller and buyer of the product.



Thank you.

Health Industry Business Communications Council (HIBCC)

Website: www.hibcc.org

Email: info@hibcc.org

For more information, please call 1-877-GET-HINS.