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April 21, 2014

Food and Drug Administration
Office of the Commissioner
Division of Dockets Management (HFA-305)
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2014-N-0200, Standards for the Interoperable Exchange of Information for Tracing of Human, Finished, Prescription Drugs, in Paper or Electronic Format; Establishment of a Public Docket

Dear Sir/Madam:

The American Society of Health-System Pharmacists (ASHP) is pleased to submit comments to the Food and Drug Administration (FDA) on the above docket in response are in response to the Agency's request for information on standards for interoperable exchange of drug information as published in the Federal Register on February 20, 2014.[1] The Society's comments focus on a number of the thirteen questions raised by the FDA in the Federal Register notice, as well as additional information that Agency should consider as it implements Title II of the Drug Supply Chain Security Act (DSCSA).

ASHP is the national professional organization whose 40,000 members include pharmacists, pharmacy technicians, and pharmacy students who provide patient care services in acute and ambulatory care settings, including hospitals, health systems, and clinics. For more than 70 years, the Society has been on the forefront of efforts to improve medication use and enhance patient safety.

General Comments

While the DSCSA outlines critical steps to identify and trace prescription drugs through the distribution supply chain in the US, the state of current bar code encoding structures in the US makes the notion of this tracking somewhat difficult, if not impossible to consider. Without resolution to these issues, it is likely to be impractical to achieve this level of tracking.

[1] Federal Register. No. 34. Vol. 79. Pages 9745 – 9747.

In order for tracking to succeed, the tracking entity must know the National Drug Code (NDC) in the supply chain, when it was issued, what product it represents, what level of packaging it represents, and if and when it was retired. Currently, there is no single reliable database that contains this information. Evidence from our membership indicates that items may enter the supply chain before they are available in many commercial databases. Without addressing this issue, which would likely require that all NDC's be submitted before being released to the supply chain and retired rather than being reused, consistent and accurate tracking will be challenging.

Ideally, bar codes need to contain the NDC, the Lot number, the expiration date, and a serial number that uniquely identifies this instance of a package. This provides the additional benefit at the unit dose level in that it would make it possible for bar code systems to distinguish between scanning the same item versus separate items. A minimum of a 2-D barcode format would be necessary to sufficiently contain all of this information. Use of such a bar code at all packaging levels (including unit dose packages) would allow ready identification of the movement of unique items in any transaction.

For example, a given injection product might be packaged in a case containing separate boxes of individual vials. The case would be encoded with an NDC that represented the case; each box of would be encoded with an NDC that represented the box, and each vial would be encoded with an NDC that represented the individual vial.

- Scanning the case for a transfer would effectively record the movement of the case, the movement of each box within the case, and the movement of each vial within the case.
- Scanning a box of 10 for a transaction would record movement of the box and each of the vials it contains.
- The serial number on a vial would represent that vial uniquely. Scanning that vial bar code would record movement of that vial uniquely.

The type of NDC structure outlined above would maintain a continuous chain of evidence for the history of the products.

Further, the format in which the NDC captures this information should be standardized and universal across manufacturers so that vendors can design software that captures each unique parameter to populate the appropriate fields.

From a drug security standpoint, manufacturers could upload data on NDC, lot numbers, and expiration dates to the relevant databases to create an "active lot", which would then be picked up by the receiver's databases (wholesaler and pharmacy). If these identifiers do not line up, the receiver has an invalid barcode, indicating a potentially counterfeit product. Software used to scan both inbound *and* outbound product could be configured to flag a received product that was not on an intended shipment, or one scanned multiple times in separate locations (e.g., the real product into one warehouse and counterfeit shipment into a second warehouse).

Specific Questions Raised by the FDA

1. What types of information about transactions do you exchange? What practices, processes, or systems, either paper-based or electronic, do supply chain stakeholders use to exchange this information? Are the practices, processes, or systems based on a standard? Are they interoperable with other systems that supply chain stakeholders may be using?

   ASHP Response

   While acute care facilities utilize many dispensing, medication management, and procurement systems, they rely heavily on paper-based systems to transfer information between the vendor and the facility. For example, Information from vendors may include a manual process of scanning paper-based invoices to capture the name of a distribution center and the address, state license number, DEA number; invoice Number, NDC, drug name, package size, quantity billed, unit cost and extended costs.

2. What practices, processes or systems, either paper-based or electronic, do supply chain stakeholders use to exchange information related to prior transactions? Are the practices, processes, or systems based on a standard? Are they interoperable with other systems that supply chain stakeholders may be using?

   ASHP Response

   Electronic information may be received *retrospectively* for data warehouse activities by a health system: See Tables 1 and 2 in Attachment 1 for the level of detail currently received by that could be used to identify transactions on a *prospective* basis.

3. Do the practices, processes, or systems that supply chain stakeholders use to exchange transaction information or transaction histories include or have the ability to include lot level data?

   ASHP Response
   No. See "General Comments."

4. Are there challenges to adopting and using a system, in paper or electronic format, for the interoperable exchange of transaction information or history? How can these challenges be addressed?

   ASHP Response
   It is anticipated that there will need to be major enhancements (or replacements) to the current procurement, warehouse management, dispensing, and medication management systems with significantly increased costs for a significant number of health care organizations.

   The proposed rule would be difficult for health systems to support at the level requested (NDC, lot number, etc.) if they have centralized distribution systems. Many health systems are creating hub and spoke models to centrally purchase and distribute to other hospitals in their system. Currently, automation does not support this level of tracking and would need to be addressed without becoming overly burdensome for health systems

   FDA should clarify how tracking would be implemented for centralized IV admixture and/or repackaging services. The agency should consider if final product tracking is at the original lot numbers of the additives or if organizations would be required to assign new product, lot, and expiration date numbers.

5. Are there practices, processes, or systems that supply chain stakeholders can use now to exchange the information in the transaction statement required by the DSCSA?

   ASHP Response
   Some states have mandated pharmaceutical pedigrees although there are major differences between these laws. This lack of uniformity and variability across states has created challenges for suppliers.

6. Are there challenges to providing the transaction statement to supply chain stakeholders in either paper or electronic form? How can these challenges be addressed?

ASHP Response

In addition to the issues raised above, there is concern about what is required with the information collected. The FDA should clarify how far the agency envisions track and trace reaching, e.g., to the patient level? How is this information stored, and for what time periods. What liabilities exist for each trade partner and provider?

7. Are there standards or current practices that you would recommend for FDA to consider as a model for providing any or all of the transaction information, transaction history, or transaction statement to other supply chain stakeholders?

   ASHP Response

   There are currently two existing standards: GS1 Healthcare (Global) and Health Industry Business Communications Council HIBCC (National). Our recommendation is that the FDA mandates one standard.

Question related to capturing information that has not necessarily been addressed by the previous questions:

13. Are there other considerations related to standards for the interoperable exchange of information for tracing of human, finished, prescription drugs that have not been addressed by the previous questions? Please provide any additional information that you think could be helpful for the Agency to consider as it implements these provisions of the DSCSA

    ASHP Response

    ASHP recommends that the FDA collaborate with all applicable agencies, particularly GS1 and HIBCC, FirstDataBank (FDB) and National Council for Prescription Drug Programs (NCPDP).

The Society appreciates the opportunity to provide ASHP's perspective as the FDA begins to implement the DSCSA. Please contact me if you have any questions or wish to discuss our comments further. I can be reached by telephone at 301-664-8806, or by e-mail at ctopoleski@ashp.org.

Sincerely,

Christopher J. Topoleski
Director, Federal Regulatory Affairs

Attachment 1

Table 1 (Master Header Record)

Field	A/N	Size	Start Position	End Position	Notes
Record ID	A	2	1	2	"H1"
Partner ID	A	15	3	17	ABC Account Number used to provide the catalog.
Run Date	A	8	18	25	Date the file was created.
Vendor Number	A	5	26	30	N/A
Customer Name	A	30	31	60	ABC Customer Name.
Customer Address	A	30	61	90	ABC Customer Address.
Customer City	A	25	91	115	ABC Customer's City.
Customer State	A	2	116	117	ABC Customer's State.
Customer Zip – 5	A	5	118	122	ABC Customer's 5 Digit Zip Code.
Customer Zip – 4	A	4	123	126	ABC Customer's 4 Digit Extended Zip Code.
Distribution Center (DC) Name	A	20	127	146	Name of the ABC Distribution Center that provided the catalog.
DC Contact Name	A	60	147	206	Contact Name at the ABC Distribution Center that provided the catalog.
DC Phone Number	A	10	207	216	Phone Number of the ABC Distribution Center that provided the catalog.
Catalog Type	A	2	217	218	N/A
Transaction Type	A	1	219	219	N/A
DC Address	A	30	220	249	Address for the ABC Distribution Center that provided the catalog.
DC City	A	25	250	274	City for the ABC Distribution Center that provided the catalog.
DC State	A	2	275	276	State for the ABC Distribution Center that provided the catalog.
DC Zip – 5	A	5	277	281	5 Digit Zip Code for the ABC Distribution Center that provided the catalog.
DC Zip – 4	A	4	282	285	4 Digit Extended Zip Code for the ABC Distribution Center that provided the catalog.
Filler	A	28	286	313	N/A
DUNS Number	A	15	314	328	Reference ID that was issued by Dun & Bradstreet.
Filler	A	296	329	624	N/A
DEA Number	A	9	625	633	The Drug Enforcement Agency number assigned to a Customer.
6 Digit Account #	A	6	634	639	ABC Customer's 6 Digit Account Number.
9 Digit Account #	A	9	640	648	ABC Customer's 9 Digit Account Number.
/Change/Delete	A	1	649	649	N/A
Header/Detail/Trailer	A	1	650	650	N/A

Table 2: Detail Record

Field	A/N	Size	Start Position	End Position	Notes
Record ID	A	2	1	2	"D1"
Partner ID	A	15	3	17	ABC Account Number used to provide the catalog.
Run Date	A	8	18	25	Date the file was created.
Vendor Number	A	5	26	30	ABC Supplier Number
Maintenance Type	A	1	31	31	A=Add, C=Change, D=Delete
ABC Item Number	N	6	32	37	6 Digit ABC Item Number.
Item Size Quantity	A	8	38	45	Item Size Description.
Item Size Code	A	2	46	47	Identifies size of item: CC, DL(Deal), DR(Dram), GL(Gallon), GM(Gram), IN (Inch), LB(Pound), LT(Liter), ML(Milliliter), OZ(Ounce), PT(Pint), QT(Quart), YD (Yard).
Item Strength Quantity	A	4	48	51	A description of an item's drug potency.
Item Strength Code	A	6	52	57	A description of an item's unit makeup (MG, ML, SOL etc.).
Abbreviated Description	A	13	58	70	A 13 character field containing drug name without dose form, strengths, size or UD.
Case Quantity	N	5	71	75	The number of wholesale units in an unbroken shipping case from the Supplier.
Purchase Unit Code	N	2	76	77	This indicates the nature of the package (i.e. CS = CASE, PK = PACK).
Acquisition Cost	N	10	78	87	Customer Invoice Price.
NDDF Pack Size	N	11	88	98	First Data Bank Package Metric Size.
Fine Line Code	A	3	99	101	Numeric code used to categorize item groupings by way of generic chemical content.
NDC-UPC Number	N	11	102	112	Unique product identification number based upon the National Drug Code (NDC) system or Universal Product Code (UPC) system.
Generic Group Description	A	25	113	137	Description associated with the Generic Group Number.
Generic Group Number	A	6	138	143	An identifier assigned to a group of generic items with the same generic ingredients, route of administration, strength and drug form. Based on FDB's GCN.
Generic Therapeutic Class	A	6	144	149	Generic Therapeutic Class AHFS.
Generic Group Form Code	A	3	150	152	This identifies the physical state or properties of a Generic item. ie. TAB =Tablets; CAP = Capsules.
Generic Group Strength Quantity	A	5	153	157	A description of a Generic item's drug potency.
Generic Group Strength Code	A	6	158	163	A description of a Generic item's unit makeup (MG, ML, SOL etc.).
Unit Dose Indicator	A	2	164	165	Identifies products that are packaged in individual unit doses:

Field	A/N	Size	Start Position	End Position	Notes
					UD = Unit Dose RN = UD packed as reversed numbered.
Form Code	A	3	166	168	This identifies the physical state or properties of an item. ie. TAB =Tablets; CAP = Capsules.
Contract Quote Number	N	5	169	173	Identifies the contract associated with the contract price.
Contract Effective Date	N	8	174	181	Start date for the contract.
Contract Expiration Date	N	8	182	189	End date for the contract.
Contract Cost	A	10	190	199	Calculated value that represents the sales amount for GPP Override cost for ProGeneric items.
Supplier Name	A	30	200	229	Items Manufacturer's name.
NDDF AWP Price	N	10	230	239	First Data Bank Element that identifies their package AWP price.
Package Size Divisor	N	8	240	247	The number of component Unit Items within the Unit Item. At the lowest level the component divisor may identify the dispensing amount. Ex. A bottle of pills may breakout into 100 individual pills which may be individually dispensed.
SuperNet Price Indicator	A	1	248	248	Indicates if the item is subject to SUPERNET pricing.
List Price	N	10	249	258	ABC's List Price.
NDC-UPC-HRI Format Code	A	1	259	259	Identifies the external identifying code (NDC, HRI, UPC, or PIN) and how the 10-digit code has been converted into 11-digits. 0 = PIN 5-4-2 1 = NDC 4-4-2 2 = NDC 5-3-2 3 = NDC 5-4-1 4 = UPC 5-5 5 = UPC 5-5 6 = UPC 5-5 7 = HRI 4-6
Retail Price	N	10	260	269	Customer Retail Price
Price Category Code	A	2	270	271	N/A
Supplier Item Number	A	12	272	283	Manufacturer's catalog item number - predominately for use with home healthcare items.
Generic Item Number	N	6	284	289	ABC Generic Item Number.
Retail Pack Quantity	N	5	290	294	The number of retail units in a wholesale unit.
Generic Source Flag	A	1	295	295	Code used to indicate the type of generic source applicable to an Item. F = GPP Formulary Item B = Source and GPP Formulary

Field	A/N	Size	Start Position	End Position	Notes
					M = GPP MCP Formulary G = GPP & GPP MCP Formulary Y = Identifies a generic source item N = Identifies not a generic source item
Dispensing Unit	N	3	296	298	Number of Units based on Item Size Qty.
Dispensing UOM	A	2	299	300	The number of units typically dispensed on a prescription, i.e. 30 tablets.
Dispensing Unit Price	N	9	301	309	Full Acquisition Cost / Actual Wholesale Metric Size
Actual Wholesale Metric Size	N	8	310	317	The metric package size for an ITEM as stated by the American Druggist Bluebook. It is used to calculate the Item metric unit price. Note that this is an industry average.
Wholesale Cost	N	10	318	327	ABC's wholesale cost.
Item Minimum Quantity	N	5	328	332	The minimum order quantity for the customer determined by ABC.
Vendor Minimum Order Amount	N	8	333	340	Maximum qty that can be ordered.
Lead Time – Division1	N	3	341	343	Customer Division
Vendor Division 1 Lead Time - Days	N	3	344	346	This is the number of days from the time an order placed until it received, stocked and ready for sale.
Lead Time – Division 2	N	3	347	349	Alternate Division
Vendor Division 2 Lead Time - Days	N	3	350	352	Alternate Div-This is the number of days from the time an order placed until it received, stocked and ready for sale.
Item Status Message	A	30	353	382	Active, Allocated by Mfr, Backordered by Mfr, Discontinued by ABC, Discontinued by Mfr, Inactive, Non Stocked/Delete, Not Shipped by Supplier, New, Pending Discontinue/Count Inventory, Pending Discontinue, Recalled by Mfr, Temp Discontinued by Mfr, Temp Out/Reorder, Unavailable from Mfr.
Hazmat Code	A	1	383	383	C-NonCategorized, N-Non Hazardous, R-Regulated
Extended Description	A	12	384	395	Additional information used to distinguish a drug product, such as trademarked dosage forms, special packaging, and other unique characteristics.
AWP Wholesale Factor	N	13	396	408	A factor used in computing an items wholesale selling unit AWP. Multiplying this factor and the item-nddf-awp-price will produce the items AWP price at wholesale selling level. This may be required for the customers invoice and/or price sticker.
NDC Number	A	11	409	419	NDDF NDC Number (5-4-2 Format).
UPC Number	A	11	420	430	Unique product identification number based upon the Universal Product Code system.
Item Status Code	A	3	431	433	AC(Active), AM(Allocated by Mfr), BO(Backordered by Mfr), DB(Discontinued by ABC), DM(Discontinued by Mfr), IA(Inactive), ND(Non Stocked/Delete), NS(Not Shipped by Supplier), NW(New), PC(Pending Discontinue/Count Inventory), PD(Pending Discontinue), RM(Recalled by Mfr), TM(Temp Discontinued by Mfr), TO(Temp Out/Reorder), UM(Unavailable from Mfr).
Scannable HUN	A	11	434	444	ABC Formatted Hun Number
Brand Label Flag	A	2	445	446	Brand Item = Y Generic Item = N or blank.

Field	A/N	Size	Start Position	End Position	Notes
Price Sticker Prime Quantity	N	5	447	451	Retail Pack Qty
7 Digit Item #	A	7	452	458	ABC 7 Digit Item Number (no longer used).
Item Category Code	A	2	459	460	C2(Control Sub Cls 2) C3(Control Sub Cls 3) C4(Control Sub Cls 4) C5(Control Sub Cls 5) RX(Prescription Drug) GM(General Merchandise) HB(Health and Beauty Aids/Care) MS(Medical Surgical Supplies) OT(Over the Counter Drugs).
Wholesale Pack Type	A	2	461	462	Indicates the nature of the package (i.e. EA, CS = CASE, PK = PACK).
Item Size	N	11	463	473	Pack Size of a supplier item.
UPC Check Digit	A	1	474	474	12th character of an 11 digit UPC Number
Item Stock Status	A	1	475	475	Item Stock Status. S = Available Stock.
Minimum Order Qualifier	A	2	476	477	N/A-Always 00.
Wholesale Pack Quantity	N	5	478	482	The number of Wholesale Packs in the Suppliers "Inner Package".
Hazmat ID Code	A	6	483	488	C-NonCategorized, N-Non Hazardous, R-Regulated.
DAPA Number	A	16	489	504	The customer or buying groups' own contract number which is not the same as the Suppliers' contract number.
Scannable NDDF HUN Number	A	11	505	515	NDDF NDC Number from First DataBank
DUNS Number	A	15	516	530	Reference ID that was issued by Dun & Bradstreet.
Private Label Code	A	2	531	532	The code that indicates which type of private label the Item is packaged for.
Hamacher Fine Line Code	A	5	533	537	An industry accepted system for categorizing front-end merchandise sales; codes maintained by Hamacher Fine Line Code.
UPC Check Digit	A	12	538	549	11 digit UPC Number + 1 digit Check Digit
Drop Ship Flag	A	1	550	550	Indicates if an item will be drop shipped from the manufacturer. Y = Drop Ship.
Repack Flag	A	1	551	551	Identifies the item as a repack product. Y = Repack.
Bluebook AWP	N	11	552	562	First Data Bank element that identifies their package AWP.
MSRP	N	9	563	571	Manufacturer's suggested retail price for non-Rx items when provided by manufacturer.
Invoice Price Method	A	2	572	573	Blank – Undefined ** - Distrack Undefined BB – Supernet CC- Standard Price DD - Special Price

Field	A/N	Size	Start Position	End Position	Notes
					EE - Program Price FF - Contract Price
Pack Quantity	N	9	574	582	The number of salable units in the wholesale unit.
Private Label Indicator	A	1	583	583	Private Label Item = Y.
Special Storage Code	A	2	584	585	01 - Aerosol 02- Alcohol 03 – Refrigerated 06 - Flammable/Plastics 08 - Store & Ship Under Refrigeration 09 - Refrigerated/Do Not Freeze 11 - Keep Frozen 12 - Store & Ship Frozen.
Listed Chemical Flag	A	1	586	586	Y = Contains one or more listed chemicals.
Fine Line Code Description	A	30	587	616	Description associated with the Fine Line Code.
Bluebook Pack Size Quantity	N	11	617	627	NDDF Bluebook Pack Size of a supplier item.
Filler	A	21	628	648	N/A
Add/Change/Delete	A	1	649	649	Not currently used.
Header/Detail/Trailer	A	1	650	650	N/A