Importance of Correct Data in Health IT

Melissa Krause
Pharm.D.

Ann Johnson
Pharm.D.

EACH YEAR, MERRIAM-WEBSTER adds new words to its time-honored dictionary. In 2018, those terms included "predictive," "haptics," and "force quit." In a similar way, the vocabulary of health information technology (IT) is constantly evolving, requiring the drug compendia, which function like dictionaries of drug data, to update regularly. When a manufacturer prepares to launch a new product, the manufacturer submits clinical and pricing data to drug compendia providers. These compendia providers include the following:

- Wolters Kluwer Health's Medi-Span
- Hearst Health's First Databank
- Cerner Multum
- Elsevier Gold Standard
- Truven Health Analytics' Red Book

Compendia compile and provide drug data to their customers that utilize drug information in health IT. Drug compendia contain data on tens of thousands of products, including the product's NDC and/or other identifiers such as UPC or UDI; naming; pricing; packaging; manufacturer; therapeutic categorization; dosage form; route of administration; and a host of other fields.

For pharmacies, compendia provide the product data that drives the pharmacy management systems. These systems include drug pricing and groupings of pharmaceutically equivalent drugs for product selection, while also providing numeric fields, like usual dose and duration, that can be used to calculate the days' supply based on a given quantity of drug. Compendia also provide clinical data, including therapeutic classification. For payers, these companies provide the data to run their claims adjudication software and include drug price and data to determine whether a drug is a brand or generic (which can sometimes differ from one compendium to another; more on that later). For electronic health records (EHRs), compendia supply the drug data needed for electronic prescribing and medication histories.

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Occasionally, a drug will be launched with confusing or potentially error-prone information listed in one or more of the compendia. Different outcomes for the relevant stakeholders include the following:

WHOLESALER

Wholesalers rely on the drug compendia for their pricing information and proprietary therapeutic categorizations. The frequency of compendia updates (daily versus weekly) can affect the rebate amounts and charge-back liabilities that wholesalers owe pharmacies and manufacturers. Wholesalers also consult the drug compendia to determine which products have been categorized as being either pharmaceutically or therapeutically equivalent. Pharmaceutically equivalent refers to products that have the same active ingredient; strength or concentration; route of administration; and dosage form. Therapeutically equivalent means that products are pharmaceutically equivalent and bioequivalent, as determined by the FDA. For therapeutically equivalent products, wholesalers can identify products for source program consideration.

PHARMACY AND PHARMACY MANAGEMENT SYSTEM VENDORS

Issues at the pharmacy can arise when products are grouped together in the compendia in unexpected ways. One of the more obvious ways this can occur is when two products are grouped together and displayed as product selection options for one another when they are not therapeutically equivalent. It's a common misconception that just because two products are grouped together (sometimes described as having the same GPI [generic product identifier, as used by Medi-Span]; GCN/GSN [generic code number/generic sequence number, as used by First Databank], or similar compendia grouping), that they are substitutable for each other. This is often true, but the FDA's Orange Book ratings and state substitution laws play a key role as well. The compendia group together products that are pharma-

ceutically equivalent. Sometimes, the therapeutic use/indication can also influence whether products are grouped together. However, just because two products are deemed to be pharmaceutically equivalent does not mean that they are therapeutically equivalent and substitutable.

PRESCRIBER

As pharmacists, we're familiar with different types of errors and the confusion that can arise when e-prescriptions arrive at the pharmacy. These can include the wrong patient, wrong drug, and confusing or incorrect patient instructions, among others. However, some cases can stem from how drug products are listed in the prescriber's EHR (electronic health record) system. For example, we've seen cases where a product name was too long for the EHR system to display the full name. This cut off portion of the name that differentiated two similarly named products, can result in prescribers inadvertently choosing one product when they intended to choose another. The product name needs to be clear and easy to differentiate not only from "look alike, sound alike" drugs, but also from other dosage forms of the same product.

PAYER

For payer adjudication systems, issues can arise when the payer considers a product to have a generic substitute available but the pharmacy submitting the prescription does not. This can occur when the payer and the pharmacy subscribe to different compendia. For most prescription drugs, it is clear whether a generic exists for a given brand product. However, in some unique instances, the way a company interprets compendia data may lead one company to determine that a generic is available while the other company determines that no generic is available. This scenario may occur when there is an "authorized generic" available with no other ANDA (abbreviated new drug application)-approved generics. In some compendia, such as First Databank, authorized generic products may be considered multisource because the product is technically available from more than one source, e.g., the innovator manufacturer and its authorized generic partner. However, in other compendia, such as Medi-Span, an authorized generic with no ANDA-approved generics available may be viewed as more brand-like because the product is essentially the brand packaged in a "generic" bottle. Both compendia are providing accurate information about the product; however, the information may lead compendia customers to view the same product differently.

Manufacturers should practice strategic compendia readiness throughout their launch planning.

WHAT CAN PHARMACISTS DO?

On electronic prescriptions, if multiple similarly named products exist or multiple dosage forms of the same product are available (such as drugs that are available in both a vial and an injector device, or in a capsule and a tablet), pharmacists can check to see if the patient has received the product previously. By checking the patient's profile or asking if the patient received a sample, pharmacists can help determine the intended product to be dispensed. If that does not provide enough clarity, the pharmacist should contact the prescriber to confirm the intent.

If adjudication questions arise, pharmacists can check with the PBM (pharmacy benefit manager) to identify the correct quantity or brand/generic designation to prevent underpayment or risk of overpayment that could create an audit recoupment situation.

WHAT SHOULD MANUFACTURERS DO?

Manufacturers should practice strategic compendia readiness throughout their launch planning. Manufacturers can project during the early stages of product development how their product may appear in the compendia once it is approved and on the market. Manufacturers need to clearly delineate to healthcare professionals and patients what the product is, how to use it, and how to tell it apart from drugs that may look, sound, or be used in a similar way. Preparing for compendia listing and subsequent publishing throughout health IT is an important step in the product development and launch process. **CT**

Melissa Krause, Pharm.D., and Ann Johnson, Pharm.D., are consultants with Pharmacy Healthcare Solutions, Inc. The authors can be reached at mkrause@phsirx.com and ajohnson@phsirx.com.