Understanding Your Drug File: Package Size and Unit of Measure

We know the pharmacy industry and the prescription-filling process is complicated. In fact, ours might be the most complicated industry of all. Many factors such as state and federal regulations, third-party parameters, and pharmacy policies and procedures serve to make it so. Consequently, our pharmacy systems are expected to help us manage these factors in an effort to make prescription filling easier for the pharmacist and technician. To smooth the process, we rely on accurate data loaded into our systems to provide the precise results needed for edit checks, DUR screening, and prescription pricing. For many, all of this happens “behind the scenes.”

Most people take the drug information loaded in their pharmacy system for granted. In the majority of instances, drug information needed to fill a prescription is in the system ready to be used. Occasionally, information may not be available for a newly released brand or generic product. However, the drug database service providers, also known as “compendia,” work hard to make sure drug information available for pharmacy systems is current and accurate. Compendia serving the pharmacy industry include:

■ Elsevier/Gold Standard
■ First Databank (FDB)
■ Medi-Span, part of Wolters Kluwer Health
■ RED BOOK (Thomson Reuters)

Your software vendor works with one or more of the compendia to make sure their pharmacy system accommodates all the drug data necessary to fill prescriptions and perform systematic functions such as pricing, DUR screening, and third-party claims submission.

Here I examine two simple but key elements of drug data — a prescription drug product’s package quantity and unit of measure (e.g., milliliters, grams) — that play an integral part in pricing and reimbursement. Many products used in retail pharmacy are oral-solid dosage forms (i.e., tablets and capsules), so determining the package quantity and unit of measure is relatively simple. However, there are many products that are not oral solids and are measured using a metric decimal quantity that is not a whole number or is less than 1. Here are some examples:

■ Nasal solution 3.7 ML
■ Subcutaneous solution 0.5 ML
■ External solution 6.6 ML
■ External gel 46.6 GM

When filling prescriptions for these drugs, it may not be immediately apparent what the correct quantity is to use for filling and billing. Because this can lead to errors in payment and reimbursement, it is important for business partners to have a procedural set of guidelines to resolve issues that are fair and impartial for both parties.

Issues such as these lead to the creation of standards. From the efforts of the standards development organizations serving...
the pharmacy industry come guidelines that compendia, manufacturers, and pharmacy system software developers can follow to correctly determine the package quantity and billing unit to be used for prescription drug products. By following the guidelines, any ambiguity in distinguishing one product from another is eliminated. They also provide a means for consistent representation of drugs and other healthcare products dispensed by pharmacies for clinical evaluation, accurate invoicing, and proper reimbursement and rebate adjudication.

The introduction of innovative packaging, delivery systems, and dosage forms creates changing dynamics with regard to determining package quantities and billing units. Products that cannot be readily classified using established guidelines should be presented by manufacturers to the compendia for clarification before finalizing the product labeling and packaging. Gaining a consensus between the manufacturer and the compendia will ensure a smooth introduction of that product. Examples include:

- AndroGel metered-dose pump
- Asmanex Twisthaler
- Byetta prefilled pen for SQ injection
- Pedialyte Freezer Pops

It is important to identify products with unique quantities to be certain the proper quantity is used in dispensing and billing, ensuring correct reimbursement. This should be taken into consideration when converting your pharmacy system from an old vendor or legacy system to a new system or different vendor. If the old system used a whole-number package quantity for products listed in the compendia with a decimal quantity, then there are some considerations to keep in mind. First, system users need to understand the difference between the old and new methods for entering metric decimal quantities for prescriptions, as well as what is appropriate for the new system. Next, users need to understand if and how your data conversion process manages prescriptions previously filled for the affected products using a whole number for the dispense quantity. Last, but very importantly, you need to make sure the affected products have the correct pricing values (e.g., WAC, AWP, actual acquisition cost) loaded in the new system to ensure that the correct usual and customary price and appropriate third-party billing amount is calculated.

Practicing pharmacists do not see the results of these decisions until drug data is loaded into their pharmacy system. Input from pharmacists regarding the creation of a new drug record is not usually solicited, and many times review by the pharmacist is not needed because all of the responsible people “got it right the first time!”

Guidelines for Dosage Packaging Forms

The industry standard is based on the concept that all drug and health-related product dosage forms can be described using one of the following three billing unit values:

**Each (EA)** — Product dispensed in discrete units
- Tablets
- Capsules
- Suppositories
- Transdermal patches
- Nonfilled syringes
- Tapes
- Blister packs
- Oral powder packets
- Powder-filled vials for injection
- Kits
- Unit-of-use packages with quantity < 1 ML or < 1 GM

**Milliliter (ML)** — Product measured by liquid volume
- Liquid noninjectable products ≥ 1 ML
- Liquid injectable products in vials, ampules, or syringes
- Inhalers (when labeled “ML”)
- Reconstitutable noninjectable products at the final volume after reconstitution, except when they are in powder packets

**Gram (GM)** — Product measured by its weight
- Creams
- Ointments
- Inhalers (when labeled “gram”)

As with any set of guidelines, there may be some exceptions that must be managed with the cooperation of the compendia and the manufacturer, and the SDO acting as a mediator if needed, to reach a consensus resolution suitable to all industry parties.

However, if the compendia or users of their data are not in agreement regarding a product’s package quantity, it is usually left to the pharmacist to note any issues and the results of the problem and report them back through the appropriate channels (i.e., via the software vendor, the compendia, or a claims processor) to seek a correction. Even though this may rarely happen, knowing the background process helps you understand how the problem occurred and how it can be rectified. CT

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