

Distributor Pedigree Requirements Under Current Federal Law (PDMA)

March 2014

On November 27, 2013, President Obama signed the [Drug Quality and Security Act of 2013](#) (DQSA) into law. While the DQSA includes many provisions important to HIDA's member constituency, one of the most important provisions is the immediate preemption of the patchwork of conflicting state prescription drug pedigree laws. It is important for wholesale distributors to remember that the federal pedigree requirements within the Prescription Drug Marketing Act (PDMA) remain in place during the interim period between enactment and the start of Phase I requirements within DQSA, which begin January 1, 2015.

I thought the Drug Quality and Security Act preempted pedigree requirements for wholesale distributors. What do I need to provide my customers to ensure compliance with current federal law?

The passage of the Drug Quality and Security Act of 2013 (DQSA) immediately preempted all existing and future state pharmaceutical serialization and pedigree laws like those that previously existed in 29 states. However, prior to official implementation of the [Phase I requirements within DQSA](#), non-authorized distributors must adhere to the federal [PDMA pedigree requirements](#) outlined below until January 1, 2015.

What is the PDMA?

Congress passed the Prescription Drug Marketing Act (PDMA) in 1988. The PDMA requires that certain wholesale distributors provide an identifying statement (i.e., a pedigree) prior to each wholesale distribution of prescription drugs. Enforcement of these requirements rests with the Food and Drug Administration (FDA). Under PDMA pedigrees may be paper or electronically based.

What is considered a Prescription Drug?

The FDA defines a prescription drug as any drug (including any biological product, except for blood and blood components intended for transfusion or biological products that are also medical devices) required by federal law to be dispensed only by a prescription, including finished dosage forms and bulk drug substances.

Who is considered an Authorized Distributor of Record?

Under current federal law, an authorized distributor of record (ADR) means a distributor with whom a manufacturer has established an ongoing relationship to distribute such manufacturer's products.

Who is considered an Unauthorized/Non-authorized Distributor?

Under current federal law, an unauthorized distributor means a distributor who does not have an ongoing relationship with a manufacturer to sell or distribute its products.

Disclaimer: This document is for informational purposes only and cannot be construed as providing legal advice. Legal interpretations and questions regarding specific business operations should be directed to qualified legal/tax professionals or authorized officials.



HEALTH INDUSTRY DISTRIBUTORS ASSOCIATION

310 Montgomery Street • Alexandria, VA 22314-1516

Phone: (703) 549-4432 • Fax: (703) 549-6495 • www.HIDA.org

DISTRIBUTION
STREAMLINING HEALTHCARE™
www.streamlininghealthcare.org

How does the FDA define an “Ongoing Relationship”?

Under current federal law, an ongoing relationship means an association that exists when a manufacturer and a distributor enter into a written agreement under which the distributor is authorized to distribute the manufacturer’s products for a period of time or for a number of shipments. If the distributor is not authorized to distribute a manufacturer’s entire product line, the agreement must identify the specific drug products that the distributor is authorized to distribute.

How does the FDA define “Wholesale Distributor”?

Under current federal law, a wholesale distributor means any person engaged in wholesale distribution of prescription drugs, including, but not limited to, manufacturers; repackagers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers’ and distributors’ warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions.

What is required by un-authorized wholesale distributors under PDMA?

Wholesale distributors who have not been designated by a manufacturer as an “Authorized Distributor of Record” for that manufacturer’s prescription drug product must provide an identifying statement (i.e., pedigree) to the purchaser (i.e., another wholesale distributor, retail pharmacy or physician) before the completion of any wholesale distribution.

What information must be included on the identifying statement (i.e., pedigree)?

Under current federal law, a pedigree must include the following information:

- The proprietary and established name of the drug;
- Dosage;
- Container size;
- Number of containers;
- The drug’s lot or control number(s);
- The business name and address of all parties to each prior transaction involving the drug, starting with the manufacturer; and
- The date of each previous transaction.

Disclaimer: This document is for informational purposes only and cannot be construed as providing legal advice. Legal interpretations and questions regarding specific business operations should be directed to qualified legal/tax professionals or authorized officials.



Is an Authorized Distributor of Record required to provide information to a non-ADR to enable that non-ADR to comply with the PDMA pedigree requirements?

While the FDA strongly encourages all distributors in the prescription drug supply chain to provide pedigrees and information to trading partners for each sale, transfer, or trade of a prescription drug, under current law, ADRs are not required to provide a pedigree, whether they obtained the drug directly from a manufacturer, from an ADR, or from a non-ADR.

What if an unauthorized wholesale distributor is unable to provide transaction information involving the drug starting with the manufacturer?

The [FDA issued a rule in 2011](#) that amends the PDMA provision requiring unauthorized distributors to provide a pedigree to purchasers that traces the prescription drug back to the manufacturer. Per the 2011 rule, the FDA allows non-authorized wholesale distributors to provide transaction information back to the last authorized distributor of record above them in the supply chain (who purchased the product directly from the manufacturer) if that is the only information available.

What if my customer does not request a pedigree statement?

Under current federal law, a pedigree statement must accompany any prescription drug transaction made by a non-authorized distributor of record, regardless of whether the customer requests the documentation. A pedigree must accompany the distribution of any prescription drug from an unauthorized wholesale distributor to any purchaser (i.e., another wholesale distributor, retail pharmacy or physician) other than a consumer or patient.

What wholesale distribution transactions are exempt from the pedigree requirements?

1. Intracompany sales;
2. The purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a drug for its own use from the group purchasing organization or from other hospitals or health care entities that are members of such organizations;
3. The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization to a nonprofit affiliate of the organization to the extent otherwise permitted by law;
4. The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities that are under common control;
5. The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons;
6. The sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug under a prescription;
7. The distribution of drug samples by manufacturers' and authorized distributors' representatives;
8. The sale, purchase, or trade of blood or blood components intended for transfusion;
9. Drug returns, when conducted by a hospital, health care entity, or charitable institution or
10. The sale of minimal quantities of drugs by retail pharmacies to licensed practitioners for office use.

Disclaimer: This document is for informational purposes only and cannot be construed as providing legal advice. Legal interpretations and questions regarding specific business operations should be directed to qualified legal/tax professionals or authorized officials.



Is a pedigree required for medical devices?

In general, a pedigree is not required for medical devices; however, a pedigree is required for biological products that are also medical devices and are required by Federal law to be dispensed only by a prescription.

Is a pedigree required for drugs contained within a medical convenience kit?

Under current federal law, a pedigree is required for the drugs contained within a medical convenience kit. Although these kits may be assigned to FDA's Center for Devices and Radiological Health as the lead Center for regulatory review, separate regulations for the drug and the device components within the kit continue to apply. Because a prescription drug component of a convenience kit is separable, and in the same form as when distributed independently, it is subject to the same pedigree requirements as when it is independently distributed. The pedigree must contain the drug's lot or control number(s). To confirm that the drug's lot number is the same as that listed in the pedigree, the outer container of the convenience kit should also list the lot or control number of the prescription drug component within the kit so that the integrity of the kit's seal is not compromised to confirm that the drug's lot number is the same as that listed in the pedigree.

Is a pedigree statement required for the distribution of drug samples?

No, the distribution of drug samples is exempt from the pedigree requirements.

Is a pedigree statement required for prescription drugs that are returned from a pharmacy or a physician's office?

Yes, a pedigree is required for returns from a pharmacy or a physician's office to a wholesaler unless that pharmacy or physician's office is an ADR for those prescription drugs.

How long must a pedigree statement be retained and who is responsible for retaining it?

Under current law, a pedigree must be retained by all wholesale distributors involved in the distribution of the drug product, whether authorized or unauthorized, for 3 years.

Are repackagers and relabelers required to pass a pedigree statement?

Yes. Unless a repackager or relabeler has ADR status with the manufacturer of that product, they are required to provide a pedigree to the purchaser.

Can paper or electronic pedigrees be used in the interim?

Both paper and electronic documents and signatures may be used to meet the pedigree requirements, so long as they include the required information.

Disclaimer: This document is for informational purposes only and cannot be construed as providing legal advice. Legal interpretations and questions regarding specific business operations should be directed to qualified legal/tax professionals or authorized officials.

