

# ➤ The Promise of Science Serialized



## Commitment

Baxter views serialization as a critical element of our supply chain security program, and is taking a proactive approach across our global manufacturing and distribution network.

We follow GS1 standards for healthcare to fulfill serialization and ePedigree requirements. We believe that industry-wide adoption of these standards will:

- Improve patient safety through integrity of supply
- Support initiatives to drive increased efficiency
- Satisfy regulatory and governing agency requirements
- Provide an effective method for sharing product tracking and pedigree data

As our customer, you can be confident that BioPharma Solutions is implementing the proper systems and processes to adhere to global requirements in a timely manner.

**We are equally committed to the safety of our patients and yours.**

## Definitions:

**Serialization\*:** Serialization requires manufacturers to establish and apply to the smallest saleable unit package or immediate container a “unique identification number.”

**ePedigree:** an electronic system which provides data on the history of a saleable unit of a drug. It utilizes a unique serial number to track the historical data.

*\*As defined in 2008 California legislation; may vary per country or regulatory authority*



## Background: ePedigree

In 2008, California passed legislation (SB 1307: Ridley-Thomas, Chapter 713) that requires pharma companies to implement ePedigree systems. ePedigree is an electronic system that tracks the origin and supply history of a drug. The intent of ePedigree is to protect consumers from counterfeit drugs and contaminated medicine.

California's ePedigree requirements for prescription drugs will take effect on a staggered basis from January 1, 2015 through July 1, 2017, by the following schedule.

- 50 percent of a manufacturer's products by 2015;
- The remaining 50 percent of the manufacturer's products by 2016;
- Wholesalers and repackagers must accept and forward products with the ePedigree by July 1, 2016;
- Pharmacy and pharmacy warehouses must accept and pass ePedigrees by July 1, 2017.

## Our Approach

