

information technology providers and consulting firms have also expressed interest in participating to develop this system.

KEY PROVISIONS

The FDA has identified the key provisions (and their requirements) to be implemented over the next 10 years:

- Product identification
- Product tracing
- Product verification
- Detection and response
- Notification
- Wholesale licensing
- Third-party logistics provider licensing²

This is a huge undertaking by the FDA and the industry as a whole. Let's take a look at each provision in depth.

Product Identification

The FDA is requiring manufacturers and repackagers to put a unique product identifier on certain prescription drug packages. An example of this unique product identifier is the use of a barcode that can be easily read electronically.³ Traditional linear barcodes are used today, but are limited in their data storage capacity (Figure 4.1).

So what are certain prescription drug packages? Why are some pharmaceutical drugs exempt, while others are not? Regarding the barcode, the current FDA regulations require that certain human drug and biological



ABC-abc-1234

FIGURE 4.1

Linear barcode. (From Online Barcode Generator, TEC-IT, <http://barcode.tec-it.com/barcode-generator.aspx>. With permission.)