

# UNIQUE DEVICE IDENTIFICATION SYSTEM

## FINAL RULE AND ITS IMPACT ON OPHTHALMIC INDUSTRIES

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### AUTHOR:

**Rick VanArnam**

Regulatory Affairs Counsel

The Vision Council

[rvanarnam@barnesrichardson.com](mailto:rvanarnam@barnesrichardson.com)

(212) 725-0200 ex. 126



THE VISION COUNCIL

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## INTRODUCTION

On September 24, 2013 the U.S. Food and Drug Administration (“FDA”) promulgated its final regulations to implement a unique device identifier (“UDI”) system in the United States. These regulations are scheduled to go into effect on December 23, 2013. This guidance document focuses on those portions of the regulations that will impact members of The Vision Council, whose members produce medical devices such as eyeglass frames, prescription lenses, sunglasses, reading glasses and many low vision devices that will be required to comply with the UDI regulations. While these regulations go into effect on December 23, 2013, the implementation of the UDI requirements is staggered over time depending on the class of medical device at issue. Because most members of The Vision Council are involved with Class I medical devices, any UDI compliance required of optical frames, prescription lenses, sunglasses, reading glasses and many low vision devices will not arise until **September 24, 2018**.

## THE UNIQUE DEVICE IDENTIFIER SYSTEM

### WHAT IS THE UDI SYSTEM?

The UDI system seeks to link individual medical devices to a database containing critical information on that device. The UDI will appear on a device’s label and packaging, and by using the UDI the public and the healthcare community can track into this database and retrieve information on the distribution and use of that device. The FDA believes this linkage will assist in recalling defective devices and pinpointing safety alerts, while also allowing the public and the healthcare community to ascertain information on the product and its uses.

Compliance with the UDI system will require two steps. First, a UDI will be assigned to and affixed on the label and packaging of a medical device being manufactured in, and/or offered into interstate commerce in, the United States. The UDI will be present in two forms: a numerical or alphanumeric reference number in easy-to-read plain text and an image that can be read by a bar code scanner or other similar technology. It will consist of two data segments:

1. A device identifier, which identifies the version or model of the device and the labeler of the device; thus, each version or model of a covered device will be required to have its own device identifier and data submission to the Global Unique Device Identification Database [“GUDID”]; and,
2. A production identifier, which identifies one or more of the following items (check the complete list), when applicable:
  - a. The device’s manufacturing lot or batch;
  - b. The device’s serial number;
  - c. The device’s expiration date;
  - d. The device’s date of manufacture.

The product identifier is only required if the label of the device is required to identify a lot or batch number, a serial number, an expiration date or a manufacturing date.

Please note that the production identifier segment is not required as part of a UDI for Class I medical devices; however, the device identifier segment is.

The labeler satisfies the second requirement by submitting to the FDA certain information that will allow the FDA to identify and track the device and the labeler. This information will be posted in a new database, the GUDID, and will be publicly available but administered by the FDA. Thus, the UDI number, either the plain text or the version that can be scanned, will function as a reference number, allowing one to find data concerning the device posted on the GUDID. Each labeler must designate with the FDA a contact that will interact with the FDA regarding matters involving device identification.

## COVERAGE AND EXEMPTIONS

### WHAT PRODUCTS ARE COVERED?

In short, the rule covers all merchandise currently regulated by the FDA as a medical device. This covers a great many of The Vision Council's members' products. The final rule, however, includes many exceptions and limitations to this scope. The exceptions are discussed below.

### HOW ARE CLASS I MEDICAL DEVICES CONTAINING AN UPC TREATED?

The final regulations allow for a Universal Product Code ("UPC") to meet the requirements of the UDI for any Class I medical device. This language appears to have been swapped into the final regulations in place of the draft regulation's exemption from the UDI of all non-prescription devices sold at retail. Thus, if you are involved with a Class I medical device that carries a UPC code on its label and its device packaging, then the UPC code satisfies the UDI's labeling requirements completely. You are still obligated to populate the GUDID database with the required information, as discussed later in this document.

The Vision Council foresees that many of its members will be able to take advantage of using a UPC as the UDI, and this is especially true for those members selling over-the-counter products. Also, The Vision Council will be exploring whether the use of the lens OPC and the Electronic Frames Standard will be considered by the FDA to be the equivalent of a UPC for purposes of this exception.

### WHAT DEVICES ARE NOT COVERED AND THUS EXEMPT FROM THE UDI?

The proposed regulations have carved out many exceptions to the UDI. The exceptions are not mandatory, so a company that could use an exception can voluntarily elect to comply with UDI labeling.

The list of exceptions is as follows:

1. Any medical device that is manufactured and labeled prior to the passage of the "compliance date" for that medical device's FDA Class. The compliance date for Class I medical devices will be September 24, 2018, meaning that all Class I medical devices made and labeled before that date are exempt from the UDI; however, this exemption expires three years (September 24, 2021) from the compliance date, after which the product becomes subject to the UDI if it is still in inventory and unsold to an end user. If you are involved with Class II and Class III devices, then your compliance dates are different – September 24, 2016 for Class II and September 24, 2014 for Class III – and the grace period expires on the third anniversary of those dates.
2. Certain Class I medical devices that the FDA has by regulation exempted from good manufacturing practice requirements ("GMP"), exclusive of any continuing requirement for recordkeeping. Please note that frames, prescription lenses, sunglasses and readers have not been exempted from GMPs in the past, so it is highly unlikely these products will benefit from this exception in the future. Other Class I medical device manufacturers should check to see if the other devices they are manufacturing are exempt from GMPs.
3. Individual single-use devices of a single version or model, distributed together in a single device package and intended to be stored in that package until used, and which are not intended for individual commercial distribution. This exception covers items like a box of bandages. While the individual single-use devices are exempt, the device package is not exempt from UDI.
4. Devices used solely for research, teaching or chemical analysis and not intended for clinical use.
5. Customs devices and other devices made to meet the unique needs of a patient or physician. Note that The Vision Council inquired of the FDA whether prescription eyewear, and in particular prescription lenses, would be covered by this exemption and were advised that they would not.

6. Investigational devices
7. Veterinary medical devices that are not intended to be used for treating or preventing disease in humans
8. Devices intended to be exported from the United States
9. Devices held by the Strategic National Stockpile
10. Devices for which the FDA has established a performance standard for the device pursuant to section 514(b) of the Federal Food, Drug and Cosmetic Act
11. Devices that are packaged within the immediate container of a combination product or a convenience kit, as long as the label of the combination product or convenience kit has a UDI
12. Shipping containers
13. As mentioned above, the UDIs for Class I medical devices need only provide the device identifier segment and not the production identifiers.
14. Any device labeler can request a specific exception or alternative, which will be reviewed on a case-by-case basis.

## QUESTIONS AND ANSWERS

### WHO ISSUES A UDI?

The FDA is going to accredit one or more entities, either private nonprofit organizations or State agencies, to issue UDIs. These organizations, using international standards that have been incorporated into the final regulations (see below), will standardize the issuances of the UDIs so that they are composed of only characters from a single character set as defined by one of the incorporated international standards.

### WHAT TYPE OF MARKING WILL THE RULE REQUIRE?

For those medical devices that cannot utilize the UPC exception or one of the other exemptions to the UDI, then the rule will require that medical device labels and packaging include a UDI. As mentioned above, the UDI will be presented in two different formats on each label/package. Each UDI will be provided in plain text, and via Automatic Identification and Capture Technology (“AIDC”), such as a UPC and similar bar codes, Radio-Frequency Identification (“RFID”) tags, or near-field communications. The FDA will not be requiring any specific type of AIDC, but would allow any type of bar code, RFID, near-field or similar technology in existence now or to be developed in the future that would convey the UDI so that it can be entered into electronic patient records, etc., via an automated process. It is anticipated that most labelers will meet the AIDC requirement by providing a UPC bar code. As mentioned above, Class I medical devices that carry a UPC code satisfy both prongs of the UDI requirement, not just the AIDC one.

### IS PHYSICAL MARKING OF THE DEVICE REQUIRED?

Only one type of medical device must be directly marked with a UDI. These are devices intended for multiple uses and are intended to be reprocessed before each use.

### WHO IS RESPONSIBLE FOR LABELING THE DEVICE AND ITS PACKAGING?

The entity that causes the label to be applied to the device and its packaging, with the intent that it be commercially distributed without replacement or modification of the label, would be the labeler and thus responsible for UDI compliance. In most instances this will be the manufacturer. The labeler is also responsible for submitting the data concerning the device to the GUDID database. The information would have to be submitted to the GUDID database no later than the date that the device must be labeled with the UDI.

If a distributor re-labels a device to reflect its name and contact information with the intent that the device will be commercially distributed without subsequent replacement or modification of the label, then that distributor is not considered a labeler.

### WHAT CONSTITUTES A DEVICE PACKAGE?

A package contains a fixed quantity of devices in which devices are distributed or sold. If the quantity of devices within a package were to change, then you have a new device package. A device package includes a package within other packages but does not include shipping containers. For example, assume a device is sold in an individual package, which is sold in cartons that contain ten boxes of five devices each. In this situation, the UDI would have to be on each of the individual device packages, on the boxes that contain the five devices, and on the carton of ten boxes of five device packages. Each of these containers would be considered a distinct device package requiring the presence of the UDI.

### THE UDI SYSTEM IS TO BE BASED ON EXISTING STANDARDS.

To ensure that the UDIs are unique, compatible and accessible in both the United States and in international commerce, the proposed regulation will incorporate by reference four international standards that involve information interchange: ISO/IEC 646:1991; ISO/IEC 15459-4: 2006(E); ISO/IEC; ISO/IEC 15459-4: 2008; and, ISO/IEC/15459-6:2007. UDIs are to be issued and identified in a manner consistent with one of these existing international standards.

For example, the FDA recognizes that the UDI system should be based as much as possible on existing device identification systems. Two examples of existing systems are UPC codes and the Global Trade Identification Number operated by the international not-for-profit association known as “GS1”, and the Health Industry Bar Code identifier system operated by the Health Industry Business Communications Council. The agency estimates that between 35 to 50 percent of medical devices used in the United States already conform to one of these systems for creating unique identifiers used by the healthcare industry. The proposed UDI system will allow continued use of such systems as long as the bodies that administer those systems apply to the FDA for accreditation.

#### HOW ARE DATES ON LABELS TO BE PRESENTED?

Consistent with international standards and the EU, in those situations where a date must be provided on a device label, it is to be presented as Year-Month-Day. The year will be expressed in four digits, and month and day in two.

#### WHAT INFORMATION MUST A LABELER SUBMIT INTO THE GUDID?

All transmissions into GUDID must be done electronically unless a waiver has been granted. The information to be submitted includes:

1. The name of the labeler;
2. A telephone number or email address for the labeler’s designated contact;
3. The name of the issuing agency used by the labeler to assign its UDIs;
4. The device identifier portion (see definition above) of the UDI assigned to a particular model or version;
5. If substituting a new device identifier for a previously-reported one, the device identifier previously used for that model or version;
6. The proprietary, trade or brand name of a device as it appears on the label of the device;
7. Any version or model number that appears on the label of the device;
8. If the device is labeled as sterile, then a statement to that effect;
9. If the device contains rubber latex, then a statement to that effect;
10. If the device is available in different sizes, then the size and unit of measurement for that particular model or version as it appears on the label;
11. The type of production identifiers (see definition above) that appear on the label of the device – note that all Class I medical devices have been exempted from the requirement of identifying production identifiers.
12. The FDA premarket submission number or a statement to the effect that the device is exempt from premarket notification;
13. The FDA device listing number for the device;
14. The Global Medical Device Nomenclature (“GMDN”) – the GMDN is an existing system of generic indicators and corresponding definitions used to identify medical devices. The GMDN database has been made publicly available for use in populating the GUDID, and a module will be integrated into the GUDID through which a labeler can search for and select the proper GMDN at the time it reports data into the GUDID; and
15. The total number of individual devices contained in a device package.

## HOW LONG MUST A LABELER RETAIN RECORDS?

Each labeler will be required to retain records linking the UDIs to its devices for a period of time no less than three years after the date that the labeler ceases to market that particular version or model. These records must be available for production to the FDA upon specific request. The final regulation does not state whether the original paper records are required to be maintained or if alternative electronic storage would be allowed.

## WHO WILL HAVE ACCESS TO THE GUDID?

The FDA intends to make the information in the GUDID publicly available in a searchable format via its website. It has determined that the information submitted into the GUDID is not confidential, personal, or a trade secret. The only exception to this is that the FDA device listing number, which will not be made publicly available.

## IMPLEMENTATION TIMELINE

### WHEN WILL THE RULE BECOME EFFECTIVE?

UDI labeling for Class III medical devices (Class III being the most sensitive) will take effect one year after the publication of the final rule, in other words, September 24, 2014; Class II are being phased in over three years – September 24, 2016; Class I, which will include most of The Vision Council members' products, are being phased in over five years – September 24, 2018. As discussed above, medical devices produced and labeled before their respective compliance dates can remain in inventory for three years beyond their compliance dates before needing to comply with the UDI.

The data reporting requirements of GUDID are being phased in on the same timetable.

## QUESTIONS

If you are interested in more information about this topic, please contact:

### **Regulatory Questions:**

Greg Chavez, vice president of member services, at [gchavez@thevisioncouncil.org](mailto:gchavez@thevisioncouncil.org) or (703) 740-1399.

### **Legal Questions:**

Rick Van Arnam, Legal Counsel for Regulatory Affairs, at [rvanarnam@barnesrichardson.com](mailto:rvanarnam@barnesrichardson.com) or (212) 725-0200, ex. 126.

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