FDA's Unique Device Identification (UDI) System

with Jay Crowley

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Hello and welcome, my name is Jay Crowley, I'm Senior Advisor for Patient Safety in FDA's Center for Devices and Radiological Health, and I'm here today to talk to you about FDA's Unique Device Identification System proposed regulation. I'm going to go through, at a fairly high level, how we anticipate the UDI system is going to work. I encourage everyone to take a look at the proposed regulation and, in particular, to take a look at the questions at the end of the preamble in which we ask very specific questions of both industry and other stakeholders and are very much interested in your response to those questions. So let's get started.

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FDA developed the Unique Device Identification proposed regulation in response to a requirement in the 2007 FDA Amendments Act in which we were required to create this UDI system. We also did this to support a number of our other post-market and other regulatory systems that we have in place.

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Before I get into the specific UDI requirements, I want to draw your attention to a date-formatting requirement that is also in the UDI regulation. We received a number of letters over the years expressing concern about the way that dates are presented on device labels. These dates include, for example, expiration dates or manufacturing dates. And the concern is that dates are often presented in multiple formats. And so, for example, does 10/12 mean October 12th of a particular year? Or does it mean December 10th? And so to address this specific concern, we have created a very specific date format requirement for device labels. And again, this applies to any date that is on a device label. The format is the traditional format that we see in the U.S. – month/day/year. Month needs to be presented in a three-letter format. So, for example, January would be J-A-N. There would always be a day, so a number from 1 to 31, followed by a 4-digit year. We understand that this is different than the way that some manufacturers currently present dates on labels, and so we look forward to any comments that come in from manufacturers or other stakeholders about this requirement. Importantly, unlike the other UDI requirements, which are phased in over a number of years, this particular date-formatting requirement is effective one year after publication of the final rule.

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Moving on, we'll spend some time now talking about how we envision the UDI system working. There are basically four steps that I'll talk about and I'll spend some time going into details on each one.

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First of all, device manufacturers have to create a UDI code, and they're going to create this code according to a set of standards under the ISO 15459 heading.

And basically, what these standards do is create methods and guidelines for how issuing agencies work. There's more information about issuing agencies in the proposed rule, but we will accredit issuing agencies to provide UDI codes to device manufacturers and we expect, in particular, two issuing agencies that are currently very active in the device space, GS1 and HIBCC, to become issuing agencies under FDA's UDI system.

Device manufacturers would create and maintain their UDI code, and this is different, for example, than how the FDA's NDC system works where FDA passes out the NDC labeler codes. This system is one in which these international standards organizations will pass out manufacturer prefixes or labeler codes to manufacturers to develop their own UDI codes. And this was done primarily to support other initiatives that we're working on to develop a globally-harmonized approach to UDI. Importantly, there are two parts to the UDI, and this will come up later, so there's the Device Identifier and the Production Identifier. The Device Identifier identifies a specific manufacturer's version or model of a device, and it is analogous, if you will, to an NDC number or UPC code. The Production Identifier is however that device is currently controlled. So, if you were to look on the label of the device and you see a lot number and expiration date, those are the Production Identifiers and therefore that is the information that would be part of the UDI code. If there was a serial number or some other identifying information then that's what would become part of a Production Identifier.

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The manufacturer takes that code and applies it to all levels of packaging, and again, each level of packaging is unique and therefore has its own UDI, unique UDI code. And they apply that down to the lowest level or patient use of that particular product. Default location, as the statute dictates, is the label of the device. So if the manufacturer wants to put the UDI somewhere other than the label of the device, then that is an exception and we'll talk more about alternative placement and exceptions in a moment. The UDI needs to be both human readable and encoded in some form of AIDCT technology, linear bar codes, two-dimensional bar codes, RFID. We do not intend in the regulation to identify any specific technology. We're remaining technology neutral. We expect that the device industry, working through the issuing agencies and with their stakeholders, will identify appropriate technologies that should be used for different device types. In addition to the label requirement that I've just described, there are some devices that also require direct part marking, and this is something very specific where you actually apply the UDI to the individual device so that the UDI is available long after the device is removed from its package. And there are three categories of devices that are subject to direct part marking. What we call long-term implantable devices, those are devices intended to be implanted in a patient for greater than 30 days. Devices that are intended to be used more than once and sterilized between patient use. So those devices, for example, reusable surgical instruments, would need to be direct part marked, and stand-alone software would also need to be identified in a way that allows us to find the UDI, again, long after that software has been removed from its package.

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There are a number of exemptions that we have created proactively to reduce the cost and burden of implementation for device manufacturers. There are a number of exemptions here beyond the alternative placement exemption process that we have.

I'm going to highlight some of these – there are a number – but I do want to draw your attention to a few in particular. The first one is that Class 1 medical devices are not required to have their Production Identifiers embedded in the UDI. So remember, there's a Device Identifier and a Production Identifier for Class 1 medical devices. The only thing that is required is the device identifier. Another exemption is for devices that are sold at retail.

So devices other than prescription devices that are made available for purchase at retail establishments are exempt completely also from the UDI requirements. We have also exempted completely GMP, Good manufacturing Practices exempt Class 1 devices. And you can find a list of these devices associated with the UDI regulation on our website.

In addition, we have created an exemption for Class 1 medical devices – Class 1 single use medical devices – that are all the same model or version that are distributed together, typically in something like a shelf pack. (In this case, the individual device…) so, for example, a bandage and a box of bandages would not have to have a UDI on the individual bandage, rather than the UDI could be on the next higher level of packaging. I have a couple of examples of how we envision UDI would work.

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In this one, you'll see a linear bar code in the bottom middle of this label. This is a UDI built according to the GS1 standard. You can see that there's a parenthetical 01 followed by 14 digits. That's the device identifier. And you can see after that, that there's a parenthetical 10 and 17, and that's the lot number and expiration date of this particular device. Again, if this device had a serial number instead of a lot number, we would see the serial number there. And if it was not a device that had an expiration date, then we would not have an expiration date in there. All of this information has been put together into one bar code. This is called "concatenation".

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In the next example, you'll see that there are two linear bar codes presented, and again, perfectly reasonable way to implement UDI. The top bar code, again, a UDI built according to the GS1 standard. You can see a parenthetical 01, and fourteen digits that follow. That is the device identifier of this device, and again, this is a product that's controlled by lot and expiration date. So in the bottom bar code, you can see the lot number and expiration date. Just for example purposes, in the lower right-hand corner is a two-dimensional bar code called a "data matrix." We're starting to see more of these, for example, in retail. Though the manufacturer, in this case, has not used it for UDI, they could, in lieu of the linear bar codes, really use the data matrix for the AIDC requirements of UDI.

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The final example is the UDI built according to the HIBCC standard. The top linear bar code, again, very similar to the previous example, contains the Device Identifier information and the bottom bar code contains the lot number and the expiration date of this particular product. Again, a perfectly reasonable implementation of how we envision UDI working.

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We've talked primarily about medical devices, but I also want to touch on combination products and kits. For those devices whose primary mode of action is of a device, and that typically means that the device is regulated by CDRH, those combination products and their constituent parts would need to have their own UDI. Again, there is an exception here, and so for those constituent parts that are either physically, chemically or otherwise combined with the other constituent parts, such that you can't use them without each other, then the constituent part does not need its own UDI. The combination product itself would still need its own UDI but in those cases, the constituent product would not.
UDI also applies to kits. Now from FDA's perspective, kits are only medical devices, so if you have a group of medical devices that you're distributing, for example, as a surgical kit, the kit itself would need its own UDI and each part, or each device within that kit would also need its own UDI. And again we have an exception here. For those devices that are intended only for single use within this kit, that single-use device would not need its own UDI.

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And finally, the third part of the UDI system….So we've talked about the UDI code, we've applied the code to the label of the device and we've talked about direct part marking-- so the third part of this is what we're calling "the global UDI database", and if you remember back to the first point, we talked about the Device Identifier and the Production Identifiers. We are not collecting dynamic information here, only static information. So for each Device Identifier, the manufacturer would be responsible for submitting this information. So it's some basic identifying information to help end users use the device safely. So there's, again, some basic, make, model, brand trade-name information, some size information, how the device is packaged and how many are in there, how the device is controlled-- so again, we're not collecting lot numbers or serial numbers, but we want to know what a user would expect to find on the label of the device-- some contact information, the global medical device nomenclature term, the GMDN term would be submitted. GMDN, as name implies, is a global nomenclature being used by regulators worldwide. This is the first time that FDA has used this particular system and there's more information about GMDN in the proposed rule and I draw your attention to that. We also want to know whether the device is package sterile, whether it contains latex. For those devices that are subject to FDA premarket scrutiny, we want the 510K, PMA or other premarket authorization number as well as FDA's listing number. So as part of the registration and listing process, manufacturers receive a listing number for their devices. We are collecting that. However, that is the only piece of information that we are not making publically available because FDA uses that for other regulatory purposes.

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Here is a high level schematic of how we envision FDA's UDI database working. We have tried to simplify the process by which manufacturers will submit the data, so there's a number of different ways that manufacturers can do that.

We expect that small and medium manufacturers will use our web-based interface to submit information. You can go online. There's a user name and password and you can go on and enter information, manage your records that way.
Larger manufacturers who have many UDIs, we expect will submit information using the bulk system that we have, which is based on the Health Level Seven Structured Product Labeling, HL7SPL standard. Other parts of FDA use this now for submission of information, and there's more information about this both in the proposed rule and on our website. And for those manufacturers who are participating in other data systems and have third parties that are managing their UDI data for them, those third parties can submit the data on their behalf to the FDA database as well. As I mentioned, manufacturers are required to submit this data. We do make, except for the listing number, all that data publically available for various stakeholders to use. They can go online. They can search. They can download whatever data they're interested in. If you're interested, you can also download the entire database to populate your internal systems. So there's a number of different ways that users can interact with the UDI database.

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And finally, implementation. Implementation is based on premarket risk class. Again, this is the proposed regulation. So after the publication of the final rule, manufacturers of Class 3 devices will have one year to meet all of the UDI requirements that I've talked about. For those devices that they're currently distributing, importantly this does not apply to devices that already on the market, so this is not retroactive, but only those devices that manufacturers are currently distributing. So Class 3 devices, one year after publication of the final rule. Class 2 devices, three years after publication of the final rule. And Class 1 devices, finally, five years after publication of final rule. Importantly, when it comes to direct part marking, those requirements come into effect two years after the effective date for those classes of devices. So for example, if you have a Class 1 device that's subject to direct part marking, the label requirements and the database requirements come into play one year after publication final rule. Direct part marking requirements then would come into effect three years after publication and final rule.
And for those devices that primarily are dispensed through pharmacies, for example, diabetes care products that to date have carried either NDC or NHRIC, the National Drug Code or National Health Related Item Code numbers, as your effective date comes into play for your class of device, you will no longer be allowed to use these national numbering systems. So we're phasing out the use of NDC or NHRIC numbers completely for all medical devices over the implementation of UDI.

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Thank you again for listening to this presentation. We look forward to your comments to the proposed rule. Instructions on how to provide comments are available on our website, and I encourage you to submit those comments to us. The comment period is 120 days, so four months after publication of the proposed rule is the comment period for this UDI regulation. And again, if you have any questions or concerns, please feel free to contact us.

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After we receive all those comments, we will consolidate all those and take those into account and create a final rule, and we'll try to get that final rule out as soon as we can in order to facilitate implementation. And we will hold other kinds of training moving forward – webinars and conferences – in order to inform both industry and health care systems on how we expect UDI will work and to get response to the proposed rule.

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If you have any questions, we encourage you to contact us. My contact information is on the first slide. There's a lot of information on the UDI website, so I encourage you to take a look at: www.fda.gov/udi. There's not only information on the proposed rule, but there's also information on all the work that we've been doing over the years on the development of the UDI system. If you have any questions, you can also contact DSMICA at the address and phone number there, and the web address – the email address at the bottom is one that the UDI team monitors. So, again, I encourage you to send us any questions or comments that you have on the proposed rule.

I thank you for your time and I look forward to working with all of you in the future. Thank you.
