

Vocabulary Task Force/Clinical Operations Workgroup
Draft Transcript
August 13, 2012

Presentation

MacKenzie Robertson – Office of the National Coordinator

Good afternoon everyone. This is MacKenzie Robertson in the Office of the National Coordinator. This is a meeting of the HIT Standards Committee's Clinical Operation Workgroup and the Vocabulary Task Force. This call is a public call and there will be time for public comment at the end, and the call's also being transcribed, so please make sure you identify yourself before speaking.

I'll now take roll of the Vocabulary Task Force. Jamie Ferguson?

Jamie Ferguson – Kaiser Permanente – Vice President, Health IT Strategy & Policy

Present.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Jamie. Betsy Humphreys?

Betsy Humphreys – National Library of Medicine – Deputy Director

Present.

MacKenzie Robertson – Office of the National Coordinator

Thanks Betsy. Don Bechtel?

Don Bechtel – Siemens Health Services

Present.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Don. Christopher Chute? Bob Dolin? Floyd Eisenberg? Patricia Greim? John Halamka? Stan Huff?

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer

Present.

MacKenzie Robertson – Office of the National Coordinator

Thanks Stan. John Klimek? Clem McDonald? Stuart Nelson? Stuart, I believe you're on the line. Marjorie Rallins?

Marjorie Rallins – American Medical Association – Director, Current Procedural Terminology Clinical Informatics

Present.

MacKenzie Robertson – Office of the National Coordinator

Thanks Marjorie. Dan Vreeman? Jim Walker? Andrew Wiesenthal? And Doug Fridsma? And Marjorie Greenberg?

Marjorie Greenberg – National Center for Health Statistics – Chief, Classifications and Public Health Data Standards

I'm here.

MacKenzie Robertson – Office of the National Coordinator

Thanks, Marjorie. Are there any staff on the line?

Farrah Darbouze – Office of Science and Technology Policy

This is Farrah Darbouze from Office of Science and Technology.

MacKenzie Robertson – Office of the National Coordinator?

Farrah.

Amy Gruber – Centers for Medicare and Medicaid Services – Program Analyst

Amy Gruber, CMS.

Anthony Oliver – Health Resources and Services Administration

Anthony Oliver, HRSA.

MacKenzie Robertson – Office of the National Coordinator

Thanks Anthony. Okay, now I'll switch to the Clinical Operations Workgroup. Jamie Ferguson, you're here. John Halamka? Don Bechtel, I know you're here. Chris Chute? Martin Harris? Elizabeth Johnson? John Klimek? Nancy Orvis? Wes Rishel? Cris Ross? Joyce Sensmeier? Karen Trudel? Jay Crowley? And Terrie Reed?

Terrie Reed – Food and Drug Administration – Policy Analyst

Here.

MacKenzie Robertson – Office of the National Coordinator

Thanks Terrie. Are there any other staff from the Clinical Operations Workgroup on the line?

Okay Jamie, I'll turn it over to you.

Jamie Ferguson – Kaiser Permanente – Vice President, Health IT Strategy & Policy

Okay, well, thanks very much MacKenzie. So the, um, the purpose of this call is to receive an overview of the NPRM for the UDI, which is going to be presented by Terrie Reed from the FDA and to have clarifying discussion on the, the points that are presented just so that we make sure we have an understanding of what the rule is, what's propo-, what's proposed rule is, um, and how it might work in uh, in and around EHR systems. Then the idea is that we will have a subsequent call; there's a lengthy comment period, so we have, um, several months before comments really are due. I believe it's November 7 and, um, I believe it's November 7th the comments are due and so subsequent to this call, after having a little bit of time for reflection we'll have a second call to develop any proposed comments that we want to recommend from these workgroups that we would recommend to the HIT Standards Committee in their September meeting, or potentially comments that we wish to make to the Policy Committee for consideration; for example on functional requirements that might make use of the UDI. So that's the scope of this call and the, the next call. Are there any questions or discussion on that?

MacKenzie Robertson – Office of the National Coordinator

So Jamie, this is MacKenzie. Um, I just wanted to, um, see if you could repeat once again, are you looking to present in the September committee meetings or possibly not—

Jamie Ferguson – Kaiser Permanente – Vice President, Health IT Strategy & Policy

Yes, so the idea is that we we're hoping that we could, um, develop, um, rec— if there are any recommended comments that we want to make or any comments that we want to recommend to the Standards Committee, um, that we would make those in the September, in the September meeting.

MacKenzie Robertson – Office of the National Coordinator

Okay, so September 19th –

Jamie Ferguson – Kaiser Permanente – Vice President, Health IT Strategy & Policy

Yeah.

MacKenzie Robertson – Office of the National Coordinator

The Standards Committee? Okay.

Jamie Ferguson – Kaiser Permanente – Vice President, Health IT Strategy & Policy

Yes, yep. I mean I, I think we could still do October and still make the comment deadline, but, um, but I, I don't see any reason to wait personally.

MacKenzie Robertson – Office of the National Coordinator

Okay, and would there be separate comments to the Policy Committee you were saying?

Jamie Ferguson – Kaiser Permanente – Vice President, Health IT Strategy & Policy

Well there may be, and that's one of the things that we would want to discuss and consider.

MacKenzie Robertson – Office of the National Coordinator

Okay, so there's a September—

Jamie Ferguson – Kaiser Permanente – Vice President, Health IT Strategy & Policy

So for example— so for example, I mean I think that at present the, ah, the proposals for Stage 3, at least that I've seen, do not have specific requirements for tracking, reporting capabilities related to implants, and so that's an example of something where we may want to make a recommendation to the Policy Committee.

Uh, so are there any questions, any other questions, comments, or, or discussion on the, the agenda? And if not, then Terrie, I'm going to turn it over to you and request on the web the presentation of the slides.

Terrie Reed – Federal Drug Administration/Center for Devices and Radiological Health – Senior Public Health Analyst

Thank you, Jamie. Um, thanks for letting me tell you about Unique Device Identification, Notice of Proposal Making. Um, if you'd go to the next slide. I'm Terrie Reed, I'm sorry, Associate Director of Informatics at FDA Center for Devices and Radiological Health, ex-officio member of the Clinical Operations Workgroup, so I've met several of you. I'll just start out with some background, um, just to get us all up to the same page nowhere UDI has come from and where we are today, and then talk about the details of the proposed rules.

So it has been a long journey, since 1999 with the IOM report and in 2004 the FDA barcode rule; I won't go through all of this, but you can see that we've spent, um, up until 2012, in July when we had the proposed rule come out, and as Jamie said, November 7, 2012 the comment period closes, and in May of 2013, um, we expect, ah, based on what's in the FDA, ah, fudasia, I call it, expect UDI final rule to be published May 2013. I'll go over a specific timeline at the end of the discussion. Next slide.

So this is the piece that's in italics, is it's what's in the new legislation in 2012. The, ah, regular text was 2007, so you can see there have been some modifications and those are specific. The original, um, legislation did not have specific dates, ah, so you can see that those have been added and that's why we're confident that the rule will be out, um, early 2013. So not later than December 31st we were to issue the proposed rule, of course that came out earlier than that, which requires the placement of the device identifier on a particular device and actual identified the device through distribution and route used.

So the second piece that's in italics says that the proposed reg will not be later than six months after that close of the comment period, which puts us to May 2013, and that there will be specific requirements around implantable life-saving and life-sustaining devices that will be different, um, and add specific dates then what was wrong originally proposed. So I'll go over those again in a few minutes, but it's not later than two years after that May 2013 date, before, before taking that as when the proposed rule comes out. Next slide.

There are also some regulations, um, with respect to FDA in terms of our labeling requirements and some conforming amendments that I'll go over just a little bit to give you an appreciation for these kinds of activities we'll be doing within the FDA Center for Devices, um, in terms of changes being made internally. Next slide.

So the UDI, um, has several components. To start with it, it is a sewed, unique device identifier code and that code will be distributed according to an ISO Standard, which is 15459. Currently entity code GF1 and an organization called HIBCC both conform to that code when they are assigning, um, unique identifiers to devices, and so they would be called issuing agencies under our proposed regulation. So the way it works is that an issuing agency is responsible for assigning the codes, not FDA, um, which is unlike 10DC numbers.

The code is then created and maintained by the manufacturer, um, there it can be concatenated, um, and it's a device in production identifier. So the device identifier piece of the code is static. It has the manufacturer make, model; I'll show you a label which distinguishes the device identifier from the production identifier. And the production identifier piece contains the serial, lot number, expiration, manufacturing date, if that appears on the device label. Next slide.

So that UDI is applied to all levels of packaging down to the lowest level, which we consider the unit of use or patient use. The default location of that UDI is on the label of the device, although we allowed direct part marking. It comes in human readable and encoded in a form for automatic ID technology, but we are not specifying that technology. We consider ourselves technology neutral, um, and for direct part marking that would appear on an implantable device, which FDA defines as greater than 30 days. If the device is intended to be used more than once and intended to be sterilized before each of those uses and if it's standalone software. So those are the three instances for direct part marking. Next slide.

We do have a risk-based approach, so this is going to be, um, a, a seven-year process, and we are not asking sponsors to add any other, um, levels of control. So if they don't have serial numbers now the device is not going to be required to add serial numbers. Same's true for lot or the expiration date, it would only be how that device is controlled at this, at currently. Um, there is a, a piece of this proposed rule we'll go over that, not all devices are going to require production identifiers at all, and there is going to be a lot of exception processes and I'll turn it to placement from the label for the UDI. Next slide.

So here's a couple of slides just showing the outline of major exemptions for the UDI. So for all Class I devices production identifiers are not going to be required, for either the UDI label or the UDI database technician. In addition to that, individual Class I single use devices, this is a mouthful, all of the single version or models that are distributed together, and are not intended for individual sale; so things like Band-Aids, the UDI is on the package. Devices other than prescription devices that are made available for purchase at a retail establishment; so things like over-the-counter devices would be exempt from UDI. Uh, GMP, that's good manufacturing practice, exempts Class I devices; there are a whole list of those. We have product codes for those, so we know which devices would be exempt there's a few others. Next slide.

So I've been talking about these device identifiers and the production identifier; this is a labeling example, so human readable form, so the, um, information in the oblong is where the UDI is, the device identifier is the top row there. So what follows the 01 is called the device identifier. On the bottom row is pieces of the production identifier for that, and that whole thing would be the UDI. So what follows the 17 is expiration date, what follows the 10 is the lot number; that can be parsed out, um, by automatic ID and then could also be read manually. Next slide.

This is just another example, unfortunately it's not very readable, but it gives, that first slide was a GS1 example; this is from that other company HIBCC, just showing that both of those are allowable and they have different formats, but they're both unique device identifiers. Next slide.

This is just a slide, what will be covered by UDI and some new kinds of concepts. The combination product, PMOA means primary mode of action, is a device, so a combination product will have its own unique device identifier and each device in that combination product will have its own UDI. So a combination product is really like a combination of a device in a drug or a combination of a device in a blood product. So here it's saying when that combination product has as its primary mode of action a device, it gets a UDI. Just a second, I lost my screen.

Sorry about that. Okay, so likewise at kit, which is composed of devices only, has its own unique device identifier and each device packaged in the kit has its own UDI. Um, the only exception is a device intended for single use would not have its own UDI. So there are a lot of rules around, um, around this and we're going to have folks here at the FDA Center for Devices working with sponsors on placement, exemptions, ah, what's the combination product, and um, and all sorts of the regulatory questions based on this. Next slide.

This slide gives what is associated with that UDI. So that UDI code will be stored in a UDI database that will be housed here at FDA, and will be publicly available for downloads. Um, we're hoping to have web services in the near future, um, and within that database what will be the code and all of the rest of these elements. Um, so things like make and model, the size of the device, device version, unit of measure, what it is controlled by. So it's important to note that while on the label of the device we will have the unique identifier, um, all the way down to what the, the lot or serial number is, if that's how it's controlled. So within the UDI database it's just going to be; is it controlled by expiration date, is it controlled by lot number, so it will be yes/no questions in the UDI database.

We'll also have something called global medical device nomenclature code and the description; that's a naming or a categorization of device, whether the device is packaged in serial, whether it's labeled as containing latex products, whether, um, am, and it's corresponding pre-market authorization number that were assigned to it by FDA, and listing number and that's just for our own internal purposes, to make sure that those devices seen submit, submitted to the UDI database are also registered and listed in our FDA registration and listing databases across validation for us. Next slide.

This gives a little bit more about the information flow. So if you start in the top left, the manufacturer of the device has two ... the ... goes across the top of the page is the actual labeling of the device, so they need to label it, give it the device identifier, the production identifier, which includes whether it's lot number and those, um, elements, and then the product goes out for distribution. Prior to going to distribution, that same manufacturer has to submit that minimum data set that I just showed you for each device identifier that they're distributing, and that they can do through two mechanisms.

One is a web-based tool that we'll have available and another is through the use of H07SPL, and that the choice of the sponsor. That information will go into an FDA database, it will have to pass the business rules, um, that UDI database is going to be publicly available, as I said. And then the arrow from the UDI database up to that FDA database is intended to show that we are integrating that information into UDI database into our other, um, databases like our adverse event database, recalls database registration listing, and those kinds of things. So really our, the UDI database is going to be seen as a source of truth for device identification. Next slide.

So this slide shows our implementation activities, um, and this is a perfect world, ah, so some of these, you know, can be delayed and we've seen that happen with UDI in the past, but we are hopeful that we can have this kind of a timeline and especially with it being set up in the legislation as it is right now. So on the far left are the database implementation activities. So you'll see that April the implementation, April of 2013, our final database will be available for submission. In May of 2013 when the final rule comes out and all the comments have been addressed, we'll consider that to be the baseline for the UDI database, you know, submission specs will be available, people will be able to start entering into the database although they could do that prior in April, but May everything will be set down.

One year from that time will be the deadline for our highest risk devices so that will include any high risk implants and life sustaining devices. That is their deadline for getting, the sponsors getting that information into the UDI database. Likewise, May 2015, based on that new wording in the legislation, all implants and life sustaining devices will be in UDID, so in May 2014, um, there will some be high risk implant devices. So by May 2015 all classes of implants and life sustaining devices will be in the UDI database. Uh, May 2016 will be the deadline for our next, next highest risk devices, Class II, and then May of 2018 for Class I devices. So you can see that this, ah, we're hoping to learn, um, from our first iteration down to May 2018 and then corresponding to all that database work, um, is the development of the UDI regulations. So, as we've said, the comments are due November 7th and that final rule will be out May 2013.

Then, um, at the same time we are, as we speak, working on several demonstration projects and Jaime talked about how UDI will work in electronic health records. We actually have, um, a demonstration project in a multi-hospital system where we are combining concept of ... and implementation of device identification into electronic health records and I'll explain that a little bit. So at this health system we are, they're going to have UDI on cardiac stents and this is going to be in the cath lab and they're actually going to trace, um, from the time those stents are received in the hospital to the time they're implanted in the patient, um, taking their systems, like their EHR, their cath lab systems, and testing out how this would actually work, and we're hoping to learn a lot about how UDI placement, um, in the electronic health record works, whether the obstacles what, what, um, do we need to be thinking about. That's all happening, um, this year and next. We'll have a lot of information to inform, um, when all of the implants are in the UDI a database and form meaningful use activities around electronic health records based on that demonstration work. Next slide.

These are all of the conforming FDA amendments, um, so each of these were, are being modified to accept UDI information in medical device reporting reports of correction, recall, premarket approvals, inner quality system regulation, all this, all this listed here. Next slide.

This just is a, an informational slide on how to submit the comments just for your reference. So we encourage those comments; um, October's great and we're hoping that we get comments by October because we don't have a whole lot of time, um, between the end of the comment period and when we need to get the final rule out.

I think the last slide is just an e-mail address if you have questions and a point to our UDI website, so I'm open for questions, concerns.

Stuart Nelson – National Library of Medicine

Terrie?

Terrie Reed – Federal Drug Administration/Center for Devices and Radiological Health – Senior Public Health Analyst

Yes?

Stuart Nelson – National Library of Medicine

This is Stuart Nelson. I realize the, the real significance and importance of having the Universal id-, Device Identifier. I'm concerned with how the FDA is going to be sure that their u-, universe, their UDI database is proofed and maintained and complete. Um, certainly my experience with the Food and Drug Administration's NDC codes has been that the information that the FDA has, has not been complete and I'm concerned about having identifiers running around that are not in the UDI database.

Terrie Reed – Federal Drug Administration/Center for Devices and Radiological Health – Senior Public Health Analyst

Right.

Stuart Nelson – National Library of Medicine

So do you want to comment on what the FDA proposes to do to ensure that these devices, identifiers are in the database?

Terrie Reed – Federal Drug Administration/Center for Devices and Radiological Health – Senior Public Health Analyst

Well we are actually in conjunction with this, I am leading a, a project called Master Data Management, um, within the center, and so one of our, it's a strategy for establishing these sources of truth. So in one answer to your question, we are going to have a rule called the Data Steward, Data Custodian of the UDI database that will be monitoring the quality of that data. It's also unique that, um, I think, and you can correct me if I'm wrong, but the UDI database will be at the FDA, will be public facing, so if there are discrepancies, um, there's one place to report; it is going to be considered the source of truth. So if there are other UDI's around, they would not be the source of truth.

Stuart Nelson – National Library of Medicine

Okay, so, so suppose, you know suppose I'm a cardiac surgeon and or cardiologist and I go in and I re-, remove a pacemaker and it has an identifier on it, but I look in the UDI database and it's not there. Now what's truth; what's in the database or what's in my hand?

Terrie Reed – Federal Drug Administration/Center for Devices and Radiological Health – Senior Public Health Analyst

The database is supposed to be the truth because, because all inventory control systems are going to, I mean this is our long-term vision that the supply chain is going to be tied to this, um, and that that will be one, another mechanism; there will be multiple mechanisms for keeping the UDI database as the source of truth. So what that particular, ah, you know—

Jamie Ferguson – Kaiser Permanente – Vice President, Health IT Strategy & Policy

So this communication—

Terrie Reed – Federal Drug Administration/Center for Devices and Radiological Health – Senior Public Health Analyst

We can't control everything,

Jamie Ferguson – Kaiser Permanente – Vice President, Health IT Strategy & Policy

Yeah, so this is Jamie. It sounds though as if Stewart's bringing up the point about a, about sort of transition planning.

Terrie Reed – Federal Drug Administration/Center for Devices and Radiological Health – Senior Public Health Analyst

Right.

Jamie Ferguson – Kaiser Permanente – Vice President, Health IT Strategy & Policy

For—

Terrie Reed – Federal Drug Administration/Center for Devices and Radiological Health – Senior Public Health Analyst

Right. And that's one, I mean this is one of the reasons you know, for these demonstration projects we can't, you know, as you know we can regulate the sponsors, um, but it gets tougher as we reg, as we try to regulate, we don't regulate, um, you know, the healthcare industry, the hospitals themselves. That's why we're trying to have partnerships, um, you know with the electronic health records so that if they, if we can set up mechanisms that electronic health records point to UDI database and that kind of thing, um, that we've had more assurance that we don't have these kind of rogue systems being built.

W

Um, but—

Jamie Ferguson – Kaiser Permanente – Vice President, Health IT Strategy & Policy

So, I'm sorry this is Jamie, I'm sorry, were you done with that one?

Terrie Reed – Federal Drug Administration/Center for Devices and Radiological Health – Senior Public Health Analyst

I am.

Jamie Ferguson – Kaiser Permanente – Vice President, Health IT Strategy & Policy

Okay. Let me bring up something. I have a couple of different questions that sort of ... But let me just bring up one on, um, the exclusions, because as we've talked about, um, vocabulary and identifiers in particular for drugs one of these is that are there are over-the-counter medications that get prescribed routinely and that we would want to then be able to identify, um, as, as prescribed medications and I'm wondering if there's an analogy to devices that are ordered through prescription, um, where you're exclusion says basically anything that sort of, as I understand it, anything that's available at retail without a prescription is excluded.

Terrie Reed – Federal Drug Administration/Center for Devices and Radiological Health – Senior Public Health Analyst

Right. Um, you know we—it probably is that scenario, I'm not an expert in that. Um, we are trying to identify over-the-counter products at FDA; it's a little, it's difficult for us, frankly, um, because it's, we don't capture that in that way, so we're kind of struggling with that concept.

Jamie Ferguson – Kaiser Permanente – Vice President, Health IT Strategy & Policy

And so you know I'm wondering, Stuart, cause I know you, you worked on that issue, I believe, in this committee for, in relation to the Rx ..., and I wonder if you have any insights on that?

Stuart Nelson – National Library of Medicine

Well certainly that, the, the things that are of concern are those things that are reimbursable through, through um, through insurance programs, um, because, ah, particularly now with the, with the ... accounts, um, if you're going to claim an exemption, a reimbursement from a savings account based on, that it's an over-the-counter device or drug, you, you need to have a doctor's prescription for it.

Terrie Reed – Federal Drug Administration/Center for Devices and Radiological Health – Senior Public Health Analyst

Hmm, interesting.

Stuart Nelson – National Library of Medicine

So that, you know for example I'm, I'm looking here and saying, well what about a glucometer?

Terrie Reed – Federal Drug Administration/Center for Devices and Radiological Health – Senior Public Health Analyst

Right.

Stuart Nelson – National Library of Medicine

Um, is a glucometer going to have a UDI?

Terrie Reed – Federal Drug Administration/Center for Devices and Radiological Health – Senior Public Health Analyst

Just over-the-counter.

Stuart Nelson – National Library of Medicine

It's an over-the-counter device. So it's—so I'm seeing that here on the, on the exemptions, the UDIs. Is that correct?

Terrie Reed – Federal Drug Administration/Center for Devices and Radiological Health – Senior Public Health Analyst

I'm sorry, somebody, I had an interruption from the operator. Can you repeat your question? I guess she cut you off.

Stuart Nelson – National Library of Medicine

Oh I'm sorry; well you know for example a glucometer is an OTC device.

Terrie Reed – Federal Drug Administration/Center for Devices and Radiological Health – Senior Public Health Analyst

Right.

Stuart Nelson – National Library of Medicine

Will it have a UDI, but—

Terrie Reed – Federal Drug Administration/Center for Devices and Radiological Health – Senior Public Health Analyst

Accor-, not according to the latest proposed rule.

Stuart Nelson – National Library of Medicine

Not according to this rule.

Terrie Reed – Federal Drug Administration/Center for Devices and Radiological Health – Senior Public Health Analyst

Right.

Stuart Nelson – National Library of Medicine

Although it may be something that people are going to be seeking reimbursement for purchasing.

Terrie Reed – Federal Drug Administration/Center for Devices and Radiological Health – Senior Public Health Analyst

It sounds like it from what you're saying.

Jamie Ferguson – Kaiser Permanente – Vice President, Health IT Strategy & Policy

And actually that, that, thank you Stuart. So that point actually leads into one of my other questions which was about the relationship or mapping of the UDI to HCPCS, um, as it might relate to the, uh the identification of devices on the, of, on the C schedules that are used by Medicare and the Medicaid programs.

M

I mean so—

Terrie Reed – Federal Drug Administration/Center for Devices and Radiological Health – Senior Public Health Analyst

Are you asking the question?

Jamie Ferguson – Kaiser Permanente – Vice President, Health IT Strategy & Policy

Yeah, I guess, I guess I'm asking that, is that, is a cross reference of that nature envisioned within the UDI database or, or is there another way that—

Terrie Reed – Federal Drug Administration/Center for Devices and Radiological Health – Senior Public Health Analyst

It hasn't been up to this point; it's not one of the attributes.

Jamie Ferguson – Kaiser Permanente – Vice President, Health IT Strategy & Policy

Okay, and I guess, I think Marjorie's on the call; do you have any thoughts on that?

W

Which Marjorie are you referring to?

W

There are people speaking to us with their mute buttons on because we're not hearing them.

W

Perhaps you could repeat the question and whom you're asking it of.

Jamie Ferguson – Kaiser Permanente – Vice President, Health IT Strategy & Policy

Okay, sorry, this is Jamie, and, and you're absolutely right. I, it was operator error on my phone. Well I'm, I'm just wondering, and I guess this is really for anybody that if, if there's, a plan for an official cross-map of the UDI identifiers to the HCPCS that are used to identify the same things, in the fee schedules as an example?

Stuart Nelson – National Library of Medicine

Jamie, this is Stuart. I have an opinion and it might be more appropriate if could do, if we're doing a mapping to do it from the GMDN identifier, which should be in the UDI database.

Jamie Ferguson – Kaiser Permanente – Vice President, Health IT Strategy & Policy

Um hmm.

Terrie Reed – Federal Drug Administration/Center for Devices and Radiological Health – Senior Public Health Analyst

Correct. That's correct.

Stuart Nelson – National Library of Medicine

Through the HCPCS.

Jamie Ferguson – Kaiser Permanente – Vice President, Health IT Strategy & Policy

Yep, I think that sounds right to me. Okay, but Terrie you, you said that's not currently envisioned within the UDI database.

Terrie Reed – Federal Drug Administration/Center for Devices and Radiological Health – Senior Public Health Analyst

No, not in this really.

Betsy Humphreys – National Library of Medicine – Deputy Director

This is Betsy. I have another question, um, and I noticed in the, the formulation of the UDI there is meaning embedded in the code that is the manufacturer is identified, is that correct?

Terrie Reed – Federal Drug Administration/Center for Devices and Radiological Health – Senior Public Health Analyst

It's ident-, well, we'd like to say that none of the code has meaning except that, that makes it unique. You know that the issuing agency works with the sponsor to have codes associated with that sponsor.

Betsy Humphreys – National Library of Medicine – Deputy Director

Okay, so, but am I going to be able to, if I had the inside knowledge to say oh, this is a device manufactured by the agency company or—

Terrie Reed – Federal Drug Administration/Center for Devices and Radiological Health – Senior Public Health Analyst

Not really, that's not the intent.

Betsy Humphreys – National Library of Medicine – Deputy Director

So, but my next question is what happens when I buy the company and continue to manufacture the device. Um, this certainly happens frequently in the drug world. I mean—

Terrie Reed – Federal Drug Administration/Center for Devices and Radiological Health – Senior Public Health Analyst

Right.

Betsy Humphreys – National Library of Medicine – Deputy Director

The medication world and they do, I think I'm right, Stuart, but you'll correct me, but we do then end up with additional or new identification numbers?

Stuart Nelson – National Library of Medicine

We are supposed to. They don't always make out new NDCs, sometimes they keep the old one.

Betsy Humphreys – National Library of Medicine – Deputy Director

Well I'm not sure that I'm necessarily in favor of it in either direction. I guess I've, I've wondered what the intent is. So therefore you could have, is your expectation, um, under the scheme that you're proposing—and I'm sorry I haven't read it in great detail yet—that in fact if, you know, XYZ company buys ABC company, they then would issue new UDIs for all the devices?

Terrie Reed – Federal Drug Administration/Center for Devices and Radiological Health – Senior Public Health Analyst

Not necessarily, which is a bad answer, but what our principle is here is the label of the device. So theoretically what the labeler on that label of the device would say it's Johnson & Johnson.

Stuart Nelson – National Library of Medicine

And now it's GE, for example.

Terrie Reed – Federal Drug Administration/Center for Devices and Radiological Health – Senior Public Health Analyst

If that label changed and it became GE, then the principle would be yes, it would need a new UDI.

Stuart Nelson – National Library of Medicine

Well it's principle—

Terrie Reed – Federal Drug Administration/Center for Devices and Radiological Health – Senior Public Health Analyst

Because in the UDI database, you know, here, here's the, here's what we would want. We would want the person who scans that device, who uses that UDI code to look up in the UDI database; we would want that code to match the name of the company with that device.

Stuart Nelson – National Library of Medicine

So another approach to doing this obviously would be to update the database rather than define a new identifier.

Terrie Reed – Federal Drug Administration/Center for Devices and Radiological Health – Senior Public Health Analyst

Right. So that's—

Betsy Humphreys – National Library of Medicine – Deputy Director

I don't know why that appeals to me more than this approach but maybe I'm wrong and—

Terrie Reed – Federal Drug Administration/Center for Devices and Radiological Health – Senior Public Health Analyst

Well part of this, too, you know, um, and—

Betsy Humphreys – National Library of Medicine – Deputy Director

Well this may be something that people want to think about more—

Terrie Reed – Federal Drug Administration/Center for Devices and Radiological Health – Senior Public Health Analyst

Right, right.

Betsy Humphreys – National Library of Medicine – Deputy Director

And ... comments.

Terrie Reed – Federal Drug Administration/Center for Devices and Radiological Health – Senior Public Health Analyst

Right.

Jamie Ferguson – Kaiser Permanente – Vice President, Health IT Strategy & Policy

Yeah, because I mean certainly you can, you can imagine a scenario where the devices are, in fact identical. But just based on their date of manufacture the, the owner of the company is different.

Terrie Reed – Federal Drug Administration/Center for Devices and Radiological Health – Senior Public Health Analyst

Right.

Betsy Humphreys – National Library of Medicine – Deputy Director

Yeah, I guess my feelings about a lot of this is if it's the same device—

Terrie Reed – Federal Drug Administration/Center for Devices and Radiological Health – Senior Public Health Analyst

Right.

Betsy Humphreys – National Library of Medicine – Deputy Director

—It would be wonderful if I've got the device as a box for the device and I bought it last year or something and it was sold this year, that I could still get to the rest of the information about the device or not begin to wonder whether my device is obsolete or something because there was no current record for it.

Terrie Reed – Federal Drug Administration/Center for Devices and Radiological Health – Senior Public Health Analyst

Well we will have history, um, it will be ..., we're using DUNS number and we're hoping DUNS number keeps up with the transfers of ownership.

Betsy Humphreys – National Library of Medicine – Deputy Director

Well at any rate I guess we should all think about this, um, as to whether there are any substantive comments, anybody, anyone whether individually or through the committee might want to, um, make on—

Terrie Reed – Federal Drug Administration/Center for Devices and Radiological Health – Senior Public Health Analyst

The comments.

Betsy Humphreys – National Library of Medicine – Deputy Director

—what approach to management of—

Terrie Reed – Federal Drug Administration/Center for Devices and Radiological Health – Senior Public Health Analyst

Right.

Betsy Humphreys – National Library of Medicine – Deputy Director

—things would actually be more helpful to them.

Terrie Reed – Federal Drug Administration/Center for Devices and Radiological Health – Senior Public Health Analyst

So it's theoretical if the DUNS number stayed the same? Does everybody know what DUNS number, Dun & Bradstreet number; that'll be the code we use for the labelers to submit to the UDI database?

Betsy Humphreys – National Library of Medicine – Deputy Director

I would have thought off the top of my head that say if GE buys Johnson & Johnson's product or vice versa that they would already have their own DUN number, an, DUNS number and they wouldn't be the same, but.

Jamie Ferguson – Kaiser Permanente – Vice President, Health IT Strategy & Policy

Yeah, that's, the question is how does, how does Dun & Bradstreet keep up the DUNS numbers?

Terrie Reed – Federal Drug Administration/Center for Devices and Radiological Health – Senior Public Health Analyst

Right. I, I think you know sometimes the DUNS number may stay the same, sometimes it may not. I mean my understanding is that there are many ways this goes.

Betsy Humphreys – National Library of Medicine – Deputy Director

Yeah, I, you know and I, I was actually thinking of the, I mean I some, at least some of the cases I was thinking of Terrie, this is Betsy again, it, were the notion that both companies still exist.

Terrie Reed – Federal Drug Administration/Center for Devices and Radiological Health – Senior Public Health Analyst

Right.

Betsy Humphreys – National Library of Medicine – Deputy Director

But I bought this product—

Terrie Reed – Federal Drug Administration/Center for Devices and Radiological Health – Senior Public Health Analyst

Right.

Betsy Humphreys – National Library of Medicine – Deputy Director

—or this subsidiary or something, and now I'm making this particular product, whether it's a drug or device, it's not that other firm, you know, sale ended business or that I acquired all of their holdings, you know.

Terrie Reed – Federal Drug Administration/Center for Devices and Radiological Health – Senior Public Health Analyst

Right. I would, I would encourage comments on it.

Betsy Humphreys – National Library of Medicine – Deputy Director

Does anyone else have any, Jamie, I don't know you're still there or not, does anyone—

Jamie Ferguson – Kaiser Permanente – Vice President, Health IT Strategy & Policy

Yes, no, I, yeah, I, no I'm here. Thanks Betsy. So, and I'll be here for another ten minutes.

Betsy Humphreys – National Library of Medicine – Deputy Director

Very good, and we will be done by then.

Jamie Ferguson – Kaiser Permanente – Vice President, Health IT Strategy & Policy

Yea, maybe we will. But I, I, Terrie, oh sorry, go ahead, was that Stuart?

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer

This was Stan.

Jamie Ferguson – Kaiser Permanente – Vice President, Health IT Strategy & Policy

Oh Stan, hi.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer

Hi. I just, you know, I would like to sort of second Betsy's approach to how these are maintained. It's, you know it's, there's a precedent there in how they label airplanes, um, and, you know, they use a manufacture and stuff, or actually I think it's the person who ordered it, or the manufacturer, one of the other is part of the, you know, the tail number on planes, but once it's established, it doesn't matter how it got established, that remains the identifier of that airplane you know, regardless of, of whatever, whoever buys it or sells it or anything else after the fact, and so this, I think we could think of this is the same way. You know it's a, it's a, if you will a strategy for how it is, how the identifier is created; once it's created, it doesn't change.

Terrie Reed – Federal Drug Administration/Center for Devices and Radiological Health – Senior Public Health Analyst

Now are you talking for one particular device, like, I mean we're not going to have relabeling—

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer

Yeah.

Terrie Reed – Federal Drug Administration/Center for Devices and Radiological Health – Senior Public Health Analyst

—of the device.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer

Yeah.

Terrie Reed – Federal Drug Administration/Center for Devices and Radiological Health – Senior Public Health Analyst

So no, there wouldn't be, we wouldn't require manufacturers go back and, and put a, another label on the same device. But what happens with devices; new models, new versions, those would definitely get a new UDI.

Betsy Humphreys – National Library of Medicine – Deputy Director

Well I'm not talking, I was thinking about this and it may be a, you know a, a maybe just to say, a, um, fictional case and, and never happens. But I was thinking of, we've been manufacturing the ABC device, it's a very good device. We've stopped for whatever reason, business reasons or scope of the company or whatever, we sell the manufacturer of this device, we sell it to somebody else. It's now being manufactured; the make or model just haven't changed here; it's the same device. Granted, there are more of them, so the specific instance of the device is different if I start the manufacturing, but really all the information that identifies the device, um, at the level of all devices of that make and model are the same except now it's manufactured by company B instead of company A. You know my own view would be there would be no reason to have a new number of this just because it's now manufactured by somebody else.

Terrie Reed – Federal Drug Administration/Center for Devices and Radiological Health – Senior Public Health Analyst

Yeah, except you know, FDA regulates the manufacture of the device and we have to track.

Betsy Humphreys – National Library of Medicine – Deputy Director

Well I'm saying you can require the manufacturer of the device to update the database—

Terrie Reed – Federal Drug Administration/Center for Devices and Radiological Health – Senior Public Health Analyst

Um hmm.

Betsy Humphreys – National Library of Medicine – Deputy Director

Not necessarily assign a new number. In fact, maybe it would be a benefit to many if you didn't assign a new number.

Terrie Reed – Federal Drug Administration/Center for Devices and Radiological Health – Senior Public Health Analyst

Definitely, um, you know add those to comments. I, I suspect there's all kinds of noodling around but—. You know there's just that one straight pass for how this is gonna work.

Jamie Ferguson – Kaiser Permanente – Vice President, Health IT Strategy & Policy

Uh, so, I'm going to have to drop off in about five minutes, but I did want to encourage some discussion about, um, how UDIs would be used in, ah, situations, including, um, a post-market surveillance, but a tracking and reporting generally in terms of how they will be useful to providers for, um, for tracking at the level for example of a hospital, um, as well as how the, the UDI identifiers, um, and the, the FDA database would actually be used in registries and sort of how their reporting ecosystem would work. Um, and, and I think this, you know, this really gets to the question of what, if any capabilities would we want to recommend for standards and certification of EHR systems, and for the functional requirements for the ability to use the UDI to, to track implants for example, within the EHR systems?

Terrie Reed – Federal Drug Administration/Center for Devices and Radiological Health – Senior Public Health Analyst

I just, I want to bring up related to that, um, the fact that we do have kind of this hard rule two years, May 2015 that all implants and licensing devices will be in the UDI database. So among all other classes of devices we don't have that, that strict subset like we do around implants. So at least the FDA we see that as an opportunity to kind of hone in, target that set of devices. One of the things we talked about, so if you're talking about tracking a device in the electronic health records, one of the things we talked about is the desire by patients and clinicians to know which devices are implanted in a particular patient, um, and that is done now through the use of cards, um, often that are given to elderly patients and lost. So when they go to their doctor or return to a Surgery Center they don't know exactly what device implant they have. Um, so, at a very kind of simple level, just being able to document that implant in a particular patient in the EHR, um, you know, it's a desired goal that could also be used, um, in registry work. That same device identification for an implant in a registry, that's what our UDI demonstration project is, it's, it's a stent in the cath lab, um, and going to a registry to do some comparative effectiveness on the stent, and in turn could be recalled around, um, implantable devices. So in our recall database we would then have the opportunity to have all of the implanted devices be captured in our own FDA recall databases and in a lot of commercial products with recall information in them. So that whole kind of total lifecycle around the device that microcosm of implanted devices could represent that and that could be, you know, could start in 2015.

Does anybody have questions around that?

Jamie Ferguson – Kaiser Permanente – Vice President, Health IT Strategy & Policy

Well I mean I think that it sounds like it's a, an obvious opportunity for, for us to recommend for this workgroup to recommend a, a functional requirement along the lines of, of tracking implants. Um, in a, in Stage 3, and so let me ask the folks on the line what do you, what do you think of that timing, um, if it were, if it were a recommendation for EHRs to be certified to have the ability to use the UDI to track implanted devices.

Betsy Humphreys – National Library of Medicine – Deputy Director

Well off the top of my head – this is Betsy – it sounds like it would be a fine idea and the timing might work well. In terms of having the device have, I mean, excuse me, having the database have all the things in it, but also there being a database in advance of that with some of them so that, you know, there could be testing and, and trial implementations and at least people being able to work with it to see, you know, to develop the capability.

Jamie Ferguson – Kaiser Permanente – Vice President, Health IT Strategy & Policy

Well, I'm sorry I, I have to drop off the call but I encourage further discussion on this, so—

MacKenzie Robertson – Office of the National Coordinator

Sorry Jamie, this is MacKenzie. I just for processing, are we going to be setting up individual workgroup calls after this—

Jamie Ferguson – Kaiser Permanente – Vice President, Health IT Strategy & Policy

No, I think, I think—

MacKenzie Robertson – Office of the National Coordinator

Because we don't have anything scheduled.

Jamie Ferguson – Kaiser Permanente – Vice President, Health IT Strategy & Policy

Right, I think one more call with both of these workgroups together, um, would, would be useful to, to discuss proposing comments to the Standards Committee.

John Halamka – Harvard Medical School

And Jamie, this is John Halamka, I've joined.

Jamie Ferguson – Kaiser Permanente – Vice President, Health IT Strategy & Policy

Oh hi, John. I apologize, I'm going to have to drop off, um, but I look forward to talking to you soon.

John Halamka – Harvard Medical School

Thank you.

Terrie Reed – Federal Drug Administration/Center for Devices and Radiological Health – Senior Public Health Analyst

Thank you, Jamie.

Betsy Humphreys – National Library of Medicine – Deputy Director

Okay, so I think where we are is, um, that we discussed here a few areas of where we might have comments on this proposal and we've, um, brought up some areas or some thoughts, initial thoughts anyway about how this might feed into Stage 3 requirements given the fact that the initial, um, requirements for, um, populating the UDI database, and, and, and ensuring that their UDIs will be focused on implantable devices. Are there any other comments or issues that, um, people on the call this afternoon would like to bring up today as fodder for the next call?

Terrie Reed – Federal Drug Administration/Center for Devices and Radiological Health – Senior Public Health Analyst

And prior to, I do, we do have that CDRH, UDI e-mail that's for questions. So if you have questions, you know, before you want us to make comments, that's a good e-mail to send it to; it's being monitored every day.

Betsy Humphreys – National Library of Medicine – Deputy Director

Okay. Thank you, Terrie. Any other comments or questions or issues that people want to people on either the taskforce or the working group want to bring up now?

If anyone is raising any at the moment you must have your mute button on.

Okay. If we're hearing none, then, um, I guess, Mackenzie, this would be the time where we could open it up for public comments.

MacKenzie Robertson – Office of the National Coordinator

Sure. Operator, could you please open up the lines for public comments?

Public Comment

Rebecca Armendariz – Altarum Institute

If you are on the phone and would like to make a public comment please press *1 at this time. If you are listening via your computer speakers you may dial 1-877-705-2976 and press *1 to be placed in the comment queue. We have no comment at this time.

Betsy Humphreys – National Library of Medicine – Deputy Director

All right, um, John Halamka that is, do you have any comments you want to make before we close this up?

John Halamka – Harvard Medical School

Well see I had thought you were going to go straight to 4:30, so with your elegant summary of how you solved all the issues but you know obviously this is a very important issue in making sure that we have this canonical database and a single, you know agreed-upon standard for naming devices is key. I certainly look forward to what you guys have heard and included today. So if you could send me an e-mail that would be great.

Betsy Humphreys – National Library of Medicine – Deputy Director

All right fine. We didn't make any grand conclusions, we heard a nice summary of the proposed rule and the, and aspects as it raised some questions, but we will be having a second call to, um, delve into this more specifically.

John Halamka – Harvard Medical School

Great, well thank you for leading and I was on NPR for the last hour or so. Sorry I couldn't join you.

Betsy Humphreys – National Library of Medicine – Deputy Director

Oh good, I hope you were doing a lot of good on NPR John, I'm sure you were.

John Halamka – Harvard Medical School

It was this health information exchange, saving lives, improving quality and reducing costs; we did our best.

Betsy Humphreys – National Library of Medicine – Deputy Director

Yeah, we were all in favor of that. Alright, everyone, you'll be getting a message about the next call.

Terrie Reed – Federal Drug Administration/Center for Devices and Radiological Health – Senior Public Health Analyst

Thank you.

W

Bye.

John Halamka – Harvard Medical School

Thank you, bye.

W

Bye.