November 7, 2012

BY ELECTRONIC SUBMISSION

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2011-N-0090; RIN 0910-AG31;
Unique Device Identification System: Proposed Rule

Dear Sir/Madam:

The American Clinical Laboratory Association ("ACLA") is pleased to provide comments to the Food and Drug Administration ("FDA") on issues related to the proposed rule, Unique Device Identification System, published in the Federal Register on July 10, 2012.[1]

ACLA is a not-for-profit association that represents the nation's leading providers of clinical laboratory services, including local, regional, and national laboratories throughout the United States. ACLA's members perform laboratory services using both FDA-regulated *in vitro* diagnostic ("IVD") test kits and laboratory-developed tests ("LDTs"). The term "LDT" describes a testing service performed by a clinical laboratory using processes developed in-house, not a test kit that is subject to regulation as a medical device. In June of 2010, however, FDA published a notice in the Federal Register stating that the agency intended to develop a framework to regulate LDTs as "devices."[2] In light of that notice, ACLA offers these comments on the proposed Unique Device Identification ("UDI") rule.

[1] 77 Fed. Reg. 40736, 40768-78 (July 10, 2012).

[2] 75 Fed. Reg. 34463, 34464 (June 17, 2010).

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I. Executive Summary

ACLA believes that the proposed UDI requirements cannot apply to LDTs because an LDT is a testing service, and not an article, physical object, or "device" subject to "label" requirements under the Federal Food, Drug, and Cosmetic Act ("FDCA"). Even if LDTs were subject to the UDI rule, however, ACLA believes that FDA should categorically exempt LDTs from the UDI rule.

Compliance with the UDI rule would be infeasible because an LDT has neither a "label" nor a "device package" on which a UDI could be placed. In addition, the complexity inherent in performing laboratory testing services would present significant challenges in creating the elements of a UDI. For example: various lots of different reagents might be used for a test, making it difficult to create a "production identifier;" LDTs are modified, sometimes to respond to physician requests for individual patients or specimens, which would require changes in the device identifier; and multiple UDIs for test panels could cause confusion.

Importantly, existing standards applicable to the accreditation of clinical laboratories already achieve many of the goals of the proposed UDI rule. For example, laboratory test records contain enough information to trace back test results to a specific patient and to specific IVD kits or reagents that were used in performing the testing services. But such information cannot feasibly be incorporated into a UDI.

Notwithstanding these considerations, to the extent FDA might determine to apply the UDI rule to LDTs, ACLA urges FDA to allow laboratories a substantial period of time for achieving compliance. It appears that in neither the proposed rule, nor the preamble, did FDA give any consideration to the difficulties of applying a UDI to an LDT. This fact, and the uncertainties concerning FDA's intention to regulate LDTs as devices, would warrant the grant of a significant period of time for laboratories to comply with the UDI rule.

In addition to making clear that the proposed rule will not be applied to LDTs, FDA should consider the expenses for laboratories that may result from the proposed rule, such as the need for expensive investments in new information systems. Additionally, FDA should clarify that laboratories are not responsible for applying UDIs to devices in their possession.

II. Background

Clinical laboratories perform testing on human specimens ordered by physicians and other health care providers as an aid in the assessment of a patient's health and to help guide care and treatment. Laboratory tests can be created under two different pathways, depending on whether they are products or services—as an IVD test kit or as an LDT.

Under the first approach, a medical device manufacturer can develop a test as a physical product and then package all of the necessary components together in an IVD kit, including the necessary reagents and other materials, plus a package insert and directions for conducting the test. Manufacturers sell these kits to laboratories, hospitals, and other health care providers who then use them to perform testing. These types of kits are classified by FDA pursuant to its medical device authority as Class I, II, or III devices, and the manufacturers are subject to the various requirements that apply to those classes of medical devices, such as registration and listing, the Medical Device Reporting regulations in 21 C.F.R. Part 803, and the Quality System Regulation of 21 C.F.R. Part 820.

A second way that a test can be introduced is when a laboratory develops an LDT. Clinical laboratories are subject to a regulatory framework established by the Clinical Laboratory Improvement Amendments ("CLIA"),[3] which is enforced and overseen by the Centers for Medicare and Medicaid Services ("CMS"). Unlike the commercial kits described above, LDTs are not physical products sold to other laboratories, providers, physicians, or patients. Laboratories create LDTs by establishing procedures for performing the tests with reagents and laboratory equipment. When the test is ordered for a specific patient, the laboratory performs the test according to its own procedures and reports the test result to the authorized person who ordered the test. The laboratory does not develop a tangible product that is sold to outside laboratories, but rather performs a testing service.

LDTs are regulated by CMS under the CLIA regulations. Pursuant to 42 C.F.R. § 493.1253, a laboratory that modifies an FDA-regulated test kit or "introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures)" must establish performance specifications and various performance characteristics (e.g., accuracy, precision, sensitivity, and specificity) for the test. Additionally, the state of New York requires approval of LDT services and any testing using modified FDA-approved or FDA-cleared assays.[4] Various accrediting organizations, such as the College of American Pathologists ("CAP"), also have requirements pertaining to LDT services.

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[3] 42 U.S.C. § 263a.

[4] *See* N.Y. Comp. Codes R. & Regs. tit. 10, § 58-1.10(g); State of New York Department of Health, Comprehensive Test Approval Policy and Submission Guidelines (Feb. 2011), *available at* http://www.wadsworth.org/labcert/TestApproval/forms/Submission_Guidelines_Policy.pdf.

III. Comments on the Proposed UDI Rule

A. An LDT is a Service, Not a Medical Device Subject to the Proposed UDI Rule

The proposed UDI rule applies to medical devices and implements Section 519(f) of the FDCA. [5] Section 519(f) directs FDA to promulgate regulations requiring the "label" of "devices" to "bear" a unique device identifier.

Section 201(h) of the FDCA defines a medical device in terms of physical objects and articles; in relevant part, it defines a "device" as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory." Section 201(k) of the FDCA defines a "label" as "a display of written, printed, or graphic matter upon the immediate container of any article." The UDI rule does not apply to LDTs, because the definition of device does not encompass professional services such as laboratory testing, and an LDT does not have a "label" or an "immediate container."

Section 519(f) also provides that a UDI "shall adequately identify the device through distribution and use." Unlike commercial IVD kits subject to FDA regulation as devices, LDTs are not physical products "distributed" to other laboratories, providers, physicians or patients. Rather, LDTs are services. As described above, laboratories create LDTs by establishing procedures for performing the tests and by completing the validation and verification activities required by CLIA and accrediting organizations. When the test is ordered, the laboratory performs the test according to its procedures and reports the test result to the physician. The laboratory does not use reagents and other supplies it acquires to build a test kit that is sold or distributed, but rather uses those supplies to perform the service and expends the reagents in the process of performing the testing services. Accordingly, the purpose of the UDI—to track a "device through distribution and use"—is not applicable to LDTs.

Thus, the UDI rule is not applicable to LDTs. LDTs do not meet the definition of a device under section 201(h) because they are a service, not a physical object. Because they are not a physical object, LDTs do not have a "label" or "immediate container" that could "bear" a UDI. Nor are LDTs "distributed" for use. LDTs therefore are not subject to the proposed UDI rule, and FDA lacks statutory authority to apply the UDI rule and other device label requirements to LDTs.

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[5] 77 Fed. Reg. at 40769 (proposed 21 C.F.R. 801.20(a)).

B. FDA Should Create a Categorical Exemption for LDTs

Even assuming that FDA has authority to apply the proposed UDI rule to LDTs, FDA should create a categorical exemption for LDTs by including them in the listed exemptions in proposed 21 C.F.R. § 801.30(a). It is simply not feasible to have a UDI for an LDT. In addition, FDA's proposed rule and preamble show no evidence that FDA has considered how a UDI would apply to an LDT. Accordingly, granting a categorical exemption for LDTs in the final rule would be appropriate.[6]

1. Applying the Proposed UDI Rule Would Be Infeasible

a) An LDT Cannot Bear a Label, and There Is No "Device Package"

The proposed rule would require that a UDI appear on the "label" and "device package."[7] Proposed 21 C.F.R. § 801.3 gives "label" the definition set forth by section 201(k) of the FDCA, which is "a display of written, printed, or graphic matter upon the immediate container of any article."[8] The proposed definition of "device package" is "a package that contains a fixed quantity of devices."[9] An LDT does not have a label, because there is no physical object upon which it can be imprinted or affixed. Likewise, there is no "device package" that contains an LDT.

Indeed, there is no medium associated with an LDT that feasibly could bear a UDI. As described above, the term "LDT" describes a testing service that is performed using

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[6] This categorical exemption would apply to any LDT that might have been submitted to FDA voluntarily for premarket review in the past, such as certain IVDMIAs, as well as to any future FDA-regulated LDT.

ACLA recognizes that the proposed rule sets forth a process to request case-by-case exceptions for devices and device types from the UDI requirements. 77 Fed. Reg. at 40770 (proposed 21 C.F.R. § 801.35). Requiring laboratories to utilize this process would be wasteful of agency and laboratory industry resources, however. Although estimates vary, there are thousands of LDTs offered by clinical laboratories. Handling exceptions on a case-by-case basis therefore would require FDA to adjudicate thousands of requests. The more efficient use of resources would be categorically to exempt LDTs from the rule, in the same manner as the devices listed in proposed 21 C.F.R. § 801.30. *See* 77 Fed. Reg. at 40770.

[7] 77 Fed. Reg. at 40769 (proposed 21 C.F.R. § 801.20). Some devices must also be directly marked with a UDI. *Id.* at 40771 (proposed 21 C.F.R. § 801.50).

[8] 21 U.S.C. § 321(k).

[9] 77 Fed. Reg. at 40768 (proposed 21 C.F.R. § 801.3).

multiple reagents and laboratory equipment according to a procedure. The various reagents and pieces of laboratory equipment used in testing have their own labeling, and placing an additional bar code on items such as test tubes or ELISA trays may interfere with the performance of a test by blocking the ability of an instrument to process or to read the test sample. For instance, when washing an ELISA tray on an automated tray washer and then reading the tray by electronic reading equipment, the instrument sensors will be blocked by a barcode, resulting in faulty or no test results. In addition, it may be physically impossible to adhere a barcode to some elements of an LDT, such as small ELISA trays. In some cases, placing barcodes on equipment will require recalibration of the test.

Reagents and equipment, which may be used to perform more than one type of test, are not assembled into a physical kit that could then be labeled in a manner similar to a commercialized IVD kit. Laboratories create procedures for testing, but these proprietary documents are used internally in conducting the test and not distributed externally, and the procedures are not specific to particular lots of reagents. Test reports are disseminated externally, but these are not "labels" in any sense, particularly as the term is defined by the FDCA. Test reports communicate the results of a completed test, and indeed typically include the results of several different tests for the same patient. The content of a test report is governed by the CLIA regulations and other applicable requirements.[10]

b) Creating a "Production Identifier" Would Be Infeasible for LDTs

FDA's proposed rule would require UDIs to be composed of two numbers: a device identifier and a production identifier. The "production identifier" would be a "conditional, variable portion" of the UDI that identifies one or more of the following: lot or batch within which a device was manufactured, serial number of a specific device, expiration date of a specific device, and the date a specific device was manufactured.[11] This number would not be required for Class I devices.[12]

ACLA believes that the production identifier requirement cannot apply to LDTs. Labs perform LDTs as services that are not "manufactured" in a lot or batch, and there is no applicable "serial number" of a "specific device," expiration date, or date of manufacture. These data elements are therefore inapt for LDTs.

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[10] 42 C.F.R. § 493.1291(c) (requiring that test reports contain various elements, including a unique patient identifier, the report date, test performed, and specimen source).

[11] 77 Fed. Reg. at 40769 (proposed 21 C.F.R. § 801.3).

[12] *Id.* at 40770 (proposed 21 C.F.R. § 801.30(c)).

An LDT typically is performed with multiple reagents and other components, each with its own lot number. In addition, the same test may be performed at different times throughout the day, and each test might be performed using different reagent lots. Therefore, an LDT typically will have more than one "lot number" associated with the test—such as one for each reagent lot used—and perhaps different combinations of reagent lots when the test is performed at various times during the day or on various days in week. Thus, it would be infeasible to provide a single "production identifier" for an LDT.

Laboratories already keep records of the reagents and equipment used in performing testing.[13] But this detailed information is not typically aggregated into a single record and is voluminous. Requiring laboratories to assemble this information into one "identifier"—even assuming it were feasible—would be overly burdensome and could require a significant investment in new information systems, without any identifiable corresponding benefit to the public health.

c) LDTs Are Modified Regularly and Could Require Regular Changes to the Device Identifier

In addition to the "production identifier," the UDI would be required to include a "device identifier." The proposed regulation defines the "device identifier" to be the "mandatory, fixed portion of a UDI that identifies the specific version or model of a device and the labeler of that device."[14] Under proposed 21 C.F.R. § 830.50, certain changes to a device would result in a new "version or model," which in turn would necessitate a new device identifier.[15]

Laboratories periodically change the procedures for performing LDTs. Such changes may be intended to address supply concerns, such as validating a new type of reagent for use in case of a backorder. Sometimes an LDT is modified to run the test on a different sample type at the request of a physician. This flexibility—to make changes to a test when needed—is part of the reason why LDTs play such an important role in the healthcare system. Requiring laboratories to obtain a new UDI every time the LDT test procedures are changed could impose a significant burden. A further concern is that accrediting agencies will not be able

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[13] *E.g.*, 42 C.F.R. § 493.1283 (requiring laboratories to maintain records of the specimen identity, data and time of receipt, records of all testing (including identity of personnel), and instrument printouts, if applicable). Accrediting organizations, such as CAP, may impose additional recordkeeping requirements. These standards are addressed below in more detail.

[14] 77 Fed. Reg. at 40769 (proposed 21 C.F.R. § 801.3).

[15] *Id.* at 40775 (proposed 21 C.F.R. § 830.50).

to rapidly issue new UDIs, so that the administrative requirement of obtaining a new UDI before implementing the test modification could slow a laboratory's ability to modify a test in response to patient-specific requests, reagent or other supply changes, or new information.[16]

d) Application of the UDI to Test Panels Would Cause Confusion

One or more LDTs might be included in a "test panel." If FDA were to require multiple UDIs for a test panel consisting of multiple LDTs, users of the UDIs could find the collection of numbers for the individual LDT and the panel itself confusing.

Such confusion could be increased when laboratories conduct test panels with both FDA-regulated IVD kits and LDTs. Presumably, the laboratory would not be considered a "manufacturer" or "labeler" of the FDA-regulated IVD test kits, so it would not be required to obtain or use a UDI for tests performed as part of the panel of tests using the kits. If the LDTs were required to have a UDI, a test panel could feature UDIs for some but not all tests.

Alternatively, if FDA were to require a single UDI for the test panel, both the device identifier and production identifier portions of the UDI could be subject to constant change, for the reasons described above. For example, if a test panel's UDI covered five different LDTs, a change in the lot of any of the reagents used for just one of those tests could necessitate a new production identifier for the entire panel.

Thus, applying the UDI rule to test panels would be extremely burdensome for laboratories, while the confusion it would engender among the healthcare community would be contrary to the goals of the UDI system.

2. Existing Standards Applicable to LDTs Achieve Similar Goals as the Proposed UDI Rule

FDA explains in the preamble to the proposed UDI rule that it could provide for more rapid identification of medical devices with adverse events, more rapid development of solutions to reported problems, more efficient resolution of device recalls, better-focused and more effective FDA safety communications, and prevention of medical errors based on confusion.[17] It is not necessary to apply the UDI rule to LDTs to accomplish these goals,

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[16] Under proposed 21 C.F.R. § 830.40, a device identifier may be used to identify only one model of a device, meaning that a new device identifier would have to be obtained before a modified device is placed into interstate commerce.

[17] 77 Fed. Reg. at 40741-42.

because these goals are accomplished under the existing CLIA regulations and standards applicable to clinical laboratories.

a) The CLIA Regulations Achieve Many of FDA's Goals for the Proposed UDI Rule

The CLIA regulations of 42 C.F.R. Part 493 touch upon every facet of a laboratory's operations. In doing so, they further many of the goals FDA seeks to achieve with the UDI rule.

The CLIA regulations impose robust recordkeeping and quality requirements, helping achieve FDA's goals of rapidly identifying problems and designing solutions to those problems. Under 42 C.F.R. § 493.1283, laboratories performing non-waived tests must adhere to a "standard" regarding test records. Specifically, the laboratory must maintain an information or record system that includes: positive identification of the specimen, the date and time of specimen receipt into the laboratory, the condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability, and the records and dates of all specimen testing, including the identity of the personnel who performed the test. In addition, the laboratory must retain "[r]ecords of patient testing including, if applicable, instrument printouts."[18] Laboratories must also establish and verify the performance specifications of tests, perform maintenance and performance checks, and calibrate and verify testing procedures.[19]

The CLIA regulations address FDA's goals of efficiently resolving recalls and rapidly notifying the public of potential device errors. Upon detecting an error in a test result, the laboratory must promptly notify the person who ordered the test and, if applicable, the individual using the test.[20] This framework helps assure that every affected person receives timely notice of an error.

In addition, CLIA's requirements for the content of test reports furthers FDA's goal of preventing medical errors based on confusion. The preamble of the proposed rule explains that a UDI in patient records could help avoid confusion regarding the particular devices used in a patient's care.[21] The CLIA regulations require test reports to specify the report date, the test performed, and test results (including units of measurement or interpretation, if

[18] 42 C.F.R. § 493.1283(b).

[19] 42 C.F.R. §§ 493.1252-.1255.

[20] *Id.* § 493.1291(k).

[21] *See* 77 Fed. Reg. 40741.

applicable), among other items.[22] As a result, physicians have a clear written (or electronic) record of the testing that has been completed for a patient, reducing the likelihood of medical errors based on confusion of laboratory tests.

b) College of American Pathologists Accreditation Imposes Requirements that Help Assure Traceability of LDTs

Clinical laboratories may choose to become accredited by various organizations approved by CMS. If a laboratory obtains a "certificate of accreditation" from CMS, it must comply with the accrediting organization's requirements.[23] These organizations generally have requirements that are more robust and detailed than the CLIA regulations.

The CAP molecular pathology checklist, for example, has specific requirements relating to tracking LDTs and their components. For each patient report, the specific methods, instruments and reagents must be "traceable."[24] Additionally, sufficient information must be documented regarding "the nature of any probe or primer used in an assay to permit interpretation and troubleshooting of test results."[25] The Chemistry and Toxicology checklist requires all calibration materials used for non-FDA cleared assays to be "documented as to quality,"[26] all calibration materials to be "properly labeled as to content, calibration values, date placed in service, and expiration,"[27] and controls to be run (and documented) for each new lot number or shipment of test materials.[28]

Likewise, the Laboratory General Checklist requires a "system to positively identify all patient specimens, specimen types, and aliquots at all times."[29] The checklist also requires laboratories to have procedures "for reporting device-related adverse patient events, as required by FDA,"[30] maintain records and materials for an appropriate time,[31] and retain reports

[22] 42 C.F.R. § 493.1291(c).

[23] 42 C.F.R. § 493.61(b).

[24] MOL.34944.

[25] MOL.34188.

[26] CHM.13125.

[27] CHM.13200.

[28] CHM.13900.

[29] GEN.40825.

[30] GEN.20371.

[31] GEN.20377.

in a manner that allows prompt retrieval of information.[32] Laboratories must also promptly notify affected parties when a test error is discovered. During routine statutorily required inspections, inspectors will ensure that there is a process for handling report errors and corrective actions and review examples to ensure compliance.[33]

c) Other Voluntary Standards Achieve Similar Goals

In addition to the CLIA regulations and the requirements of accrediting organizations, clinical laboratories observe voluntary standards that achieve several goals of the proposed UDI rule. For example, the Clinical and Laboratory Standards Institute ("CLSI") sets forth a number of voluntary standards and guidelines that further the goals of the UDI rule. One such guideline is "Laboratory Quality Control Based on Risk Management; Approved Guideline," which sets forth quality control standards that would help laboratories detect problems with supplies used in testing.[34] Another example is "Management of Nonconforming Laboratory Events; Approved Guideline," which sets forth methods to report, investigate, act on, track, and trend non-conforming events, such as failures associated with reagents and equipment.[35]

In addition, many labs choose to list their tests with the Genetic Testing Registry ("GTR"). Much like the proposed Global Unique Device Identification Database, the GTR serves as a useful database for the public to find information about specifically identified LDT genetic tests.

C. Notwithstanding that the Proposed Rule Should Not Be Applied to LDTs, if FDA Applies the UDI to LDTs, it Should Allow a Sufficient Period of Time for Achieving Compliance

For the reasons discussed above, FDA lacks authority to apply the UDI rule to LDTs, and it should create a categorical exemption for LDTs even if the agency were to conclude that LDTs are subject to the rule. Notwithstanding these considerations, if FDA applies the UDI rule to LDTs, it should allow for a sufficient period of time for laboratories to achieve compliance.

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[32] GEN.41300.

[33] GEN.41307.

[34] CLSI. Laboratory Quality Control Based on Risk Management; Approved Guideline. CLSI document EP23-A. Wayne, PA: Clinical and Laboratory Standards Institute; 2011.

[35] CLSI. Management of Nonconforming Laboratory Events; Approved Guideline. CLSI document GP32-A. Wayne, PA: Clinical Laboratory Standards Institute; 2007.

FDA does not currently regulate LDTs.[36] In 2010, however, FDA published a notice in the Federal Register stating that it intended to require laboratories offering LDTs to comply with device regulatory requirements, such as registering establishments, listing devices, and seeking 510(k) clearance or premarket approval, as applicable. FDA has not issued any proposed regulatory framework to do so, and the timing and details of any such framework are unknown. In light of this uncertainty as to the regulatory status of LDTs, it would be inappropriate to apply the UDI rule to LDTs at all, or at least until a significant period of time after adoption of such a regulatory framework.

The proposed UDI rule staggers effective dates according to the classification of the device. FDA proposes that Class III devices be labeled with a UDI by one year after publication of a final rule, Class II devices be labeled with a UDI by three years after publication, and Class I devices be labeled with a UDI by five years after publication.[37] Devices that have not been classified must be labeled with a UDI by five years after publication.[38]

In light of these uncertainties, and the challenges discussed above, FDA should not make LDTs subject to the effective dates set forth in the proposed rule. Neither FDA nor laboratories know, at this time, how many LDTs would be classified. Therefore, the phase-in schedule in the proposed UDI rule, which assumes device classifications are known, could cause significant challenges if applied to LDTs. Instead, if FDA concludes that the UDI rule would be applied to LDTs, FDA should permit laboratories five years to come into compliance with the UDI requirements after the classification of an LDT (into either class I, II, or III) first takes effect.[39]

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[36] In recent years, however, FDA has accepted and cleared 510(k) notifications voluntarily submitted for *in vitro* multivariate index assays (IVDMIAs), and has issued warning letters to laboratories that offer direct-to-consumer genetic tests.

[37] 77 Fed. Reg. at 40764.

[38] *Id.*

[39] Section 614 of the Food and Drug Administration Safety and Innovation Act requires that FDA implement the UDI rule within two years after finalization for devices that are "implantable, life-saving, and life sustaining." Pub. L. 112-144, § 614, 126 Stat. 1061 (2012). Although LDTs can play an important role in diagnosis and treatment decisions, ACLA does not believe any LDT should be considered "life-saving" or "life sustaining" within the meaning of this section. Therefore, this statutory requirement should not apply to LDTs.

D. FDA Should Consider the Expenses for Laboratories that May Result from the Proposed Rule and Clarify that Laboratories Are Not Required to Apply UDIs to Devices in Their Possession

Applying the UDI rule to clinical laboratories could result in a number of operational challenges, leading to significant costs that FDA likely has not considered in the proposed rule. These expenses could include requiring modifications to laboratory information systems and billing practices.

The UDI rule could require significant changes to laboratory information systems to allow them to capture the UDI of test kits, reagents, and equipment used in testing. For example, some laboratories, as users of medical devices, may be subject to FDA's Medical Device Reporting ("MDR") requirements for device user facilities. The proposed UDI rule would amend these regulations to require user facilities to report the UDI of a device involved in an MDR, which in turn could require laboratories to modify systems to capture the UDIs of devices used in testing.[40] Such systems would need to track the UDIs of devices used in testing performed with FDA-regulated test kits, as well as the UDIs associated with any device used to perform an LDT.

Introduction of a UDI system also could require significant changes to billing practices. Billing for laboratory services is a complex process, whether the payer is a private insurance company or a government agency. Payers eventually may require the UDI of test kits to be reported when testing services are billed, which could necessitate significant changes to standardized billing forms.[41] In addition, many laboratories would have to modify their billing systems to have a mechanism to capture and report the UDI of devices used in testing. Laboratory data comprises an estimated 60-70% percent of electronic health records in the United States. FDA has not identified or addressed how the UDI rule may affect the creation and exchange of this data.

In addition, FDA should clarify in the final rule that users of devices, such as laboratories, need not apply UDIs to devices that have been distributed and are no longer in the possession of the labeler.[42] If laboratories were required to apply UDIs to equipment in their

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[40] 77 Fed. Reg. at 40,772 (proposed amended 21 §§ C.F.R. 803.32-.33).

[41] For example, the HIPAA version 5010 837 transaction does not currently support the inclusion of a UDI data element.

[42] For example, proposed 21 C.F.R. § 801.20(a) specifies that the label of a device "shall bear" a UDI, but it does not specify who is responsible for applying the UDI. Sections of the preamble suggest that only labelers are responsible for applying a UDI, but the rule should be clarified.

inventories, the expenses could be very significant. Further, labeling some devices with a UDI, such as ELISA trays, could interfere with test performance and require recalibration.

IV. Conclusion

LDTs are services, not devices, and they therefore fall outside of the scope of the proposed UDI rule. If FDA were to conclude that LDTs are subject to the UDI rule, however, the agency should create a categorical exemption for LDTs. At the least, if FDA were to conclude that LDTs would be subject to the UDI rule and will not be exempted, it should adopt a delayed effective date for LDTs. Aside from significant feasibility problems, many of the proposed UDI rule's goals are fulfilled with respect to LDTs by mandatory standards under CLIA and CAP accreditation and voluntary industry standards that apply to laboratory testing.

In addition to making clear that the UDI rule will not apply to LDTs, FDA should consider the potential expenses of the UDI rule for laboratories and clarify that laboratories are not required to apply UDIs to devices in their possession.

ACLA appreciates FDA's attention to its concerns and would welcome an opportunity to discuss these matters in more detail.

Sincerely,

Alan Mertz
President