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G2 INTELLIGENCE **Upcoming Events**

Conference:

Lab Institute 2016
October 26-28. Hyatt Regency Washington on Capitol Hill, Washington, DC
www.labinstitute.com

FDA Releases Draft Guidance for NGS-Based Tests for Infectious Disease Diagnosis

The U.S. Food and Drug Administration (FDA) released a draft guidance mid-May to provide industry with recommendations for designing studies to establish the analytical and clinical performance characteristics of next generation sequencing- (NGS-) based tests for infectious disease diagnosis.

Generally, NGS-based tests for microbial identification and detection of antimicrobial resistance and virulence markers should be submitted to the FDA. for Class II premarket approval, although certain virus targets like hepatitis B and C, human papillomavirus, and HIV could raise classification to Class III status. The draft guidance includes tests with either targeted (e.g., panels) or agnostic sequencing approaches (e.g., direct genetic analysis from a multi-organism sample).

The need for regulatory oversight was stressed at the American Society for Microbiology's 2015 colloquium on applications of NGS for clinical microbiology as participants noted culture-based methods are being replaced with molecular methods using nucleic acid amplification and hybridization technologies.

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Industry Challenged to Create More Patient-Friendly Medical Billing System

Furthering the goals of focusing on patients, coordinating health care delivery, and making health information more accessible, the U.S. Department of Health and Human Services (HHS) has launched a new challenge for stakeholders in health care—designing a better medical bill that is easier for patients to understand. The HHS press release regarding the challenge notes "[p]eople who use health care in the U.S. today can often receive bills from multiple hospitals, doctors, labs or specialists for the same episode of care that vary in content, presentation and use of health industry jargon. Because of this, it can be difficult for patients to understand what they owe, what their insurance plan covers, and whether the bills are correct or complete."

HHS and AARP are sponsoring the initiative, *A Bill You Can Understand*, which invites stakeholders to submit designs for simpler medical bills. Win-

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FDA Releases Draft Guidance for NGS-Based Tests for Infectious Disease Diagnosis, *from page 1*

Yet, the FDA notes that NGS for infectious disease diagnosis differs from genetic testing in many ways that affects the design of regulatory approaches. For one, NGS-based tests have the potential to detect multiple infectious agents and/or resistance and virulence markers in a single human clinical specimen.

Given the nature of infectious disease diagnosis, rapid results are needed for immediate treatment decisions and delayed or incorrect initial diagnoses can have fatal consequences.

"The broad range of specimen types (e.g., urine, blood, cerebrospinal fluid (CSF), stool, sputum, etc.) and the large diversity of the infectious disease agents that can be present in the sample do not allow straightforward pre-analytical, biochemical, or bioinformatics processes," the FDA writes in the draft guidance. "Each unique specimen type may require a different nucleic acid extraction procedure, a different library preparation protocol, and even a different bioinformatics algorithm to generate the final clinical result."

Therefore, the FDA proposes using a "one system" approach for the evaluation of these diagnostics. This means the FDA will evaluate these devices as a complete system, including all component parts used from sample collection to final report of results. Components generally include specimen collection device, instruments, reagents, software (to generate the sequencing library or prepare the specimen for sequencing), the sequencing instruments (along with the associated reagents and data collection elements that generate the raw sequence reads), and the data analysis pipeline (assembly, annotation, variant calling).

Additionally, given the nature of infectious disease diagnosis, rapid results are needed for immediate treatment decisions and delayed or incorrect initial diagnoses can have fatal consequences. Since confirmatory re-testing is generally unfeasible due to the rapid nature results are put into action, the FDA proposes the use of regulatory-grade sequences as an alternative comparator method for clinical evaluation that relies heavily on public databases populated with regulatory-grade target sequences, such as the "FDA-ARGOS: FDA dAtabase for Regulatory Grade micrObial Sequences; BioProject 223 231221."

The draft guidance, which is open for public comment through Aug. 11, details expected components of submissions, including:

- Benefit-risk analysis (addresses potential for and consequences of incorrect or missed identification; incorrect or missed antimicrobial resistance marker; incorrect detection of virulence; failure to differentiate colonization from infection; and missed identification of containment)
- Intended use (including nature of target-RNA, DNA, or both; specimen types; clinical syndrome; etc.)
- Test methodology
- Ancillary reagents
- Controls
- Interpreting test results and reports (describe the computational pipeline from raw sequencing data to final report and demonstrate lockdown of the bioinformatics pipeline)
- Device validation (pre-analytical factors, device performance metrics, analytical performance, instrumentation and software, and clinical evaluation)

Takeaway: FDA proposes one-system approach to review of NGS infectious disease testing. G2

Online Tool Helps ID Rare Pathogens

Launched in 2013, MicrobeNet is a "virtual microbe library" established by the Centers for Disease Control and Prevention (CDC) that helps laboratorians identify less common bacteria and diseases. The library provides access to more than 2,400 "rare and emerging infections, bacteria and fungi." The CDC recently announced it has expanded this tool to include a new module "that allows labs to research the protein signatures of the bacteria and compare them to the rare pathogens in CDCs MicrobeNet library by using Bruker's MALDI Biotyper systems." Before, the library was searched either by DNA sequence or biochemical tests. MicrobeNet helps hospitals and public health labs identify difficult to identify pathogens and respond to public health risks.

"Traditionally, clinicians or laboratorians who needed to identify a rare bacteria or fungi or to confirm an infectious disease diagnosis with one of these organisms needed to send a sample to CDC and await test results. With MicrobeNet, they can access the information they need immediately," the CDC said in its statement announcing the update. The CDC also claims this speedier identification method provides "dramatic cost savings for clinical and public health laboratories because they no longer will need to develop their own pathogen libraries."

Users also benefit from communication with CDC experts regarding the diseases searched and access to information about antibiotic-resistance. "By quickly identifying the species of bacteria, lab staff can pass this critical information to the doctors who can use it to help make a diagnosis and select the right treatment, thus reducing the risk of their patients developing drug-resistant infections," said the CDC.

Bruker explains on its website that its MALDI Biotyper system uses "Matrix Assisted Laser Desorption Ionization-Time of Flight Mass Spectrometry to measure a unique molecular fingerprint of an organism" by targeting the proteins in microorganisms. The CDC indicates that the MALDI technology is faster and cheaper than other testing methods and helps MicrobeNet cut testing time from a week to hours. MicrobeNet is part of the CDC's Advanced Molecular Detection initiative which supports innovative approaches to identifying and protecting the public against public health threats.

Takeaway: Innovation promises to improve response to bacteria posing public health threats.

Datapalooza Highlights the Value of Data

The U.S. Department of Health and Human Services (HHS) held its annual Datapalooza this month, with a theme very familiar to the laboratory sector—the value of data and its impact on health care. The event began seven years ago and at the time only 10 datasets regarding Medicare cost and quality were publicly available. Since then, according to HHS Secretary Sylvia Burwell's keynote address, there are more than 2,100 datasets available on HealthData.gov and adoption of electronic health records has tripled. Laboratories are engaged in ongoing efforts to capitalize on the data they collect from testing and improve interoperability to facilitate more coordinated delivery of health care services. It was in furtherance of these goals that Datapalooza was launched in 2010: to "meaningfully explore[] the power and promise that open health data holds and the opportunity to see how that data can serve patients."

Burwell discussed in her keynote at the event the amount of currently open public data, which allows improvements and innovation in health care, and expressed HHS' commitment to working with and supporting industry in efforts to further data accessibility, transparency and cybersecurity. Acting Assistant Secretary for Health Karen DeSalvo, who also serves as the national coordinator for health information technology, commented on the adoption of electronic health records and potential uses of health information: "The data is crying out to be used—and consumers are demanding it. We are at an exciting inflection point—one where technology, policy and demand are poised to change the way we think about, access and use health information to improve care."

Centers for Medicare & Medicaid Services Acting Administrator Andy Slavitt issued a directive to the health care industry: "If you have a business model which relies on silo-ing data, not using standards, or not allowing data to follow the needs of patients, pick a new business model or pick a new business." Slavitt also identified best practices that are particularly relevant to the lab and pathology sector, exhorting stakeholders to 1) avoid contractual limitations that inhibit "plug and play"

ability of an information system, 2) use machine readable data that can be called up easily, 3) make patient data accessible to providers in real time "with feeds into their workflow, not your portal"; and 4) use open APIs to allow easy and early sharing of information. "At this stage, there is no room for business practices that don't match the need of patients," Slavitt said in his remarks.

Linking the data revolution to the transformation to quality care, Burwell noted that the accessibility of data allows physicians to better coordinate, deliver care to patients more efficiently, and improves decisionmaking. She and Slavitt highlighted efforts to coordinate care in new delivery models like Affordable Care Organizations and medical homes as well as new measurement methodologies to fuel new payment strategies such as the recently launched Quality Payment Program under MACRA (see *National Intelligence Report*, 5/12/16, p. 1). Finally, they emphasized the need to place patients at the center of health care and empower them to play a more active and informed role in their care. "If we want lasting transformation, we have to change how we as a nation think about care. We have to engage and empower people to take control of their health and be active partners in it," said Burwell in her keynote remarks.

Takeaway: Datapalooza highlights the ubiquity of and critical need for data in a health care industry shifting its focus, delivery methods and payment models to quality and value.

Editor's Note: HHS Secretary Burwell's, CMS Acting Administrator Slavitt's prepared remarks are available online in the HHS Blog at http://www.hhs.gov/blog/2016/05/20/health-datapalooza-new-vistas.html.

focus on: *Reimbursement*

Third Annual Release of Medicare Payment Data Furthers Transparency Regarding Lab Payments

Once again, coinciding with U.S. Health and Human Services' annual Health Datapalooza conference (see page 3), the Centers for Medicare & Medicaid Services (CMS) has released an updated public dataset regarding Medicare payments: the Medicare Provider Utilization and Payment Data: Physician and Other Supplier Public Use File (Physician and Other Supplier PUF). The release furthers the goal of transparency by making public the Medicare charges from and payments to physicians, labs and other providers. According to CMS' press release regarding the dataset: "The release of timely, privacy-protected data is especially important as the Medicare increasingly pays providers based on the quality, rather than the quantity, of care they give patients. These initiatives contribute to a wide set of CMS activities focused on achieving better care, smarter spending, and healthier people throughout the health care system."

What's new this year

CMS said it has updated the dataset and its supplemental summary tables including "Medicare Physician and Other Supplier Aggregate Table" (i.e., one record per NPI) and the "Medicare State/National HCPCS Aggregate Tables." to include standardized payment data so users can compare Medicare payment amounts across geographic areas. "Standardization removes geographic differences in payment rates for individual services, such as those that account for local wages or input prices and makes Medicare payments across geographic areas comparable."

Additionally, now researchers don't have to wait for annual extracts under Limited Data Sets (LDS) but can instead request updates to LDS claims files on a quarterly basis.

Details about the data

CMS reports the dataset includes more than 986,000 health care providers who "collectively received $91 billion in Medicare payments." CMS' website explains: "The Physician and Other Supplier PUF contains information on utilization, payment (allowed amount and Medicare payment), and submitted charges organized by National Provider Identifier (NPI), Healthcare Common Procedure Coding System (HCPCS) code, and place of service. This PUF is based on information from CMS administrative claims data for Medicare beneficiaries enrolled in the fee-for-service program. The data in the Physician and Other Supplier PUF covers calendar years 2012 through 2014 and contains 100% final-action physician/supplier Part B non-institutional line items for the Medicare fee-for-service population."

CMS has provided search functions, filters and tools to help users make sense of the vast amount of information available in the dataset.

Categories of information (columns in the database spreadsheet) include National Provider Identifier, provider name, provider credentials, entity type/gender of provider, provider address, provider type (i.e., Clinical laboratory), place of service, HCPCS code and description, number of services provided (the metrics counting the number of services varies by service), number of Medicare beneficiaries receiving the service, number of beneficiaries per day of service (this category removes double counting of beneficiaries receiving multiple services), average Medicare allowable amount, average submitted charge, average Medicare payment amount, average Medicare standardized amount.

Medicare defines the following terms used in the dataset as follows:

- Average Medicare Allowed Amount is the amount Medicare pays plus the deductible, coinsurance and any third party responsibility.
- Average Medicare Payment is the amount Medicare pays after that coinsurance and deductible are subtracted.
- Average Medicare Standardized Amount is the average amount Medicare paid after beneficiary deductible and coinsurance amounts are deducted and after the standardization of Medicare payment (i.e., removal of geographic differences in payment as discussed above) is applied.

How to Use Data

CMS has provided search functions, filters and tools to help users make sense of the vast amount of information available in the dataset. For example, users can search the data by entering a provider number, specific provider name or by searching for entity names containing a specific word. Data can also be organized using filters to search a specific type of provider in a specific state for a specific HCPCS code. Filters also allow users to compare providers to each other. Visual graphics tools improve understanding by offering a variety of ways to visually display search results. For example, once filters are applied to gather a specific set of information, that data can be visually displayed for easy comparison with bar graphs, line graphs, pie charts, bubbles and tree maps.

Privacy concerns dismissed

This dataset has been released despite concerns about privacy. No beneficiary identifying information is provided. Additionally, to prevent indirect exposure of Medicare beneficiaries, CMS indicates that any aggregated records from 10 or fewer beneficiaries are excluded from the Physician and Other Supplier PUF. HHS specifically addressed privacy concerns in a 2014 letter to the American Medical Association (AMA) explaining "the Department weighed the privacy interests of physicians and the public's interest in shedding light on Government activities and operations and has determined that the public's interest outweighs the privacy interests. The Department concluded that the data to be released would assist the public's understanding of Medicare fraud, waste, and abuse, as well as shed light on payments to physicians for services furnished to Medicare beneficiaries, which are governed by statutory requirements that CMS must follow." HHS cited the *Wall Street Journal*'s ability to use Medicare payment data to identify fraud as evidence of the public interest in the information. Therefore, it concluded "release of physician-identifiable payment information will serve a significant public interest by increasing transparency of Medicare payments to physicians, which are governed by statutory requirements, and shed light on Medicare fraud, waste, and abuse."

Additionally, because the dataset informs the public about Medicare payments, types of services paid for under Medicare, and Medicare payments to specific providers, HHS argued it fostered "a more informed debate about the appropriate Medicare payment for particular services." Finally, HHS stated publishing the data is in keeping with a shift under the Affordable Care Act toward greater transparency, coordination of care, and sharing of information to increase efficiency, quality, and value of care while lowering costs. HHS cited the various programs measuring quality of care and providing tools to help the public compare providers, as well as some state laws that require providers publicly reveal charges and payment information as evidence of the "changing nature" of what is publicly shared about physician services and payment. All this transparency means, HHS concluded, that "the physicians' privacy interest in payment data is not the same as it was over 30 years ago or even 5 years ago."

Dataset promotes fraud reporting

CMS' questions and answers about the Physician and Other Supplier PUF encourage reporting any suspected fraud found in the data. In answer to the question "What do I do if I think I've identified fraud in the Physician and Other Supplier PUF?" CMS answers: "CMS is committed to the prevention and detection of fraud and abuse in the Medicare program and partners with numerous entities in this endeavor, including federal and state law enforcement agencies, the HHS Office of Inspector General, and the U.S. Department of Justice, among others. If you suspect a potential case of Medicare fraud or abuse, please visit http://stopmedicarefraud.gov for information on how to report it." Further evidence that HHS fully encourages users to ferret out fraud using this public dataset is found in the HHS letter to the AMA cited above which emphasizes the ability of such data to reveal fraud as evidence that the public interest in this information outweighs individual physician/provider privacy interests.

Takeaway: CMS continues to promote transparency by setting an example and releasing a public accessible dataset revealing Medicare charges and payments to labs and other providers.

US Patent Office Issues Guidance Targeting Diagnostic-Related Patent Claims

With the Sequenom MaterniT21 patent litigation heading for the U.S. Supreme Court, the U.S. Patent and Trademark Office (USPTO) has requested public comment on its guidance for Examiners and the public that address patent eligibility issues relevant to the diagnostics industry. Earlier this month, the USPTO issued a notice in the federal register seeking comment on a May 2016 Subject Matter Eligibility Update and several Subject Matter Eligibility Examples for Life Sciences.

A blog posting from the Deputy Commissioner for Patent Examination Policy, Robert Bahr, explains that the life sciences examples "use hypothetical fact scenarios to illustrate exemplary analyses for subject matter eligibility in view of the Supreme Court decisions in Alice Corp., Mayo, and Myriad. The examples are designed to show various ways that patent claims can be drafted for eligibility, and thus assist patent applicants and patent examiners in resolving subject matter eligibility issues in the life sciences areas." He also indicates the examples provided regarding diagnostics were specifically requested by stakeholders.

One of the examples, #31, titled Screening For Gene Alterations, addresses issues discussed in the 2013 U.S. Supreme Court decision in Association for *Molecular Pathology v. Myriad Genetics, Inc.* Another example, #29, titled Diagnosing and Treating Julitis addresses patent eligibility for diagnostic and treatment methods for a hypothetical autoimmune disease (i.e., Julitis). Each example describes and addresses patent eligibility of multiple, actual or hypothetical patent claims. Example 29 addresses the judicial exception for law of nature or abstract ideas. Some claims were found eligible for patent protection because they "recite specific and unconventional reagents and/or treatments that amount to significantly more than the judicial exception."

An examiner memorandum was also included in the latest guidance intended to achieve more consistent determinations of subject matter eligibility. The federal register notice makes clear that the guidance materials are not "substantive rulemaking and do not have the force and effect of law" but rather set forth policy based on office interpretation of the law and recent court decisions from the U.S. Supreme Court and the Federal Circuit. The examples are intended as a teaching tool for patent examiners and the public.

The guidance and examples are available to the public on the USPTO website, www.uspto.gov. Written comments should be submitted to 2014_interim_guidance@uspto.gov and will be made available for public view on the USPTO website. The comment period is open-ended, and comments will be accepted on an ongoing basis.

Takeaway: The USPTO responds to debate regarding patent eligibility in the diagnostics arena and solicits public feedback.

Industry Challenged to Create More Patient-Friendly Medical Billing System, *Continued from bottom of p. 1*

ners will be spotlighted at the Health 2.0 Annual Fall Conference and online at the challenge website, and the winning designs will be used by several "pilot partner" health care organizations, including Geisinger Health System, University of Utah Health Care and Cambia Health Solutions. The pilot partner organizations also participate on the advisory panel involved in judging the entries. Awards will be granted to one winner for the best design that is "easiest to understand" and another award will be granted to the applicant that "designs the best transformational approach to improve the medical billing system, focusing on what the patient sees and does throughout the process." The first award for new bill design is "all about *incremental innovation:* taking bills as they exist in the current system and improving them" while the second award for billing system recommendations is "about *disruptive innovation:* blowing the doors off the way things are done today and creating something completely new that improves the patient experience." Each winner receives a $5,000 prize. Criteria explained on the challenge website include understandability, creativity, uniqueness, use of plain language and most appropriate use of information and data. Applicants are encouraged to involve patients in the design process.

A research report prepared by Mad*Pow, a design agency administering the challenge, provides challenge participants with insight into the problems they should seek to resolve with their design submissions. The report includes the results from

Commonly cited desires were for more price transparency, plain English explanations of bills, and connecting charges to insurance information.

interviews of six "pilot partner" health care organizations, other stakeholders, and patients, as well as an online survey of 355 patients. Common billing system problems identified in Mad*Pow's research included understandability, the volume of communication patients receive regarding medical bills, timing of communication, terminology used, and the fact that "Patients don't know what they don't know." With regard to communication, interviews and surveys revealed frustration due to: the number of explanations of benefits and multiple bills for the same episode of care; different statements from physician, lab and hospital for one visit; and inconsistencies between billing statements. For example, specifically with regard to lab services, the report cites a patient complaint about getting two separate bills for two parts of the same lab test and neither bill described the lab test. Desired bill components detailed in the report that relate to lab services included a need for a list of specific tests performed and their associated costs. Commonly cited desires were for more price transparency, plain language explanations of bills, and connecting charges to insurance information.

The challenge materials provided also include a patient journey map that details visually a health care experience relating to an adult's skin cancer treatment, demonstrating the patient's path through the health care delivery system from visiting the primary physician, biopsy, diagnostic lab services, and surgery. The hypothetical scenario depicted in the map "triggers six different billing streams involving claims and payments and bills between the Insurer, the Patient, PCP, Specialist Practice, Labs, Hospital system and a Third Party administering the Patient's FSA/HRA accounts."

Other resources provided to challenge participants include guidelines, checklists, regulatory information (such as IRS regulations setting forth notification requirements relevant to financial assistance policies), a summary of state law requirements for EOBs, and links to relevant state laws (e.g., Vermont, Ohio, and Wisconsin laws regarding medical bills), and a New York law addressing EOBs.

Submissions are due by Aug. 10, 2016, and winners will be announced in September. The submissions must include: 1) a "design brief" describing the submission and how it satisfies the challenge criteria, in fewer than 2,250 words; 2) a visual depiction of "what the patient sees"—including the bill, and other materials or tools available to the patient; 3) a three-minute or shorter video explaining how the submission meets challenge criteria; and 4) a journey map similar to the one discussed above demonstrating the changes to the billing process from the patient's perspective.

Takeaway: Many labs have already recognized the need to improve communication with patients by designing user friendly test result reports. HHS is now looking for industry to make similar progress on medical billing reports and systems.

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