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Covering Government Policy For Diagnostic Testing & Related Medical Services

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Health Datapalooza Coincides with Release of Medicare Utilization and Payment Data

"*[T]he goal is to transform data into information and information into insight*," said Carly Fiorina in 2004 at Oracle OpenWorld, while serving as CEO and Chair of Hewlett Packard Co. The annual Health Datapalooza, held May 31 to June 3, 2015 (Washington, D.C.), embodies the goal that Fiorina expressed, promoting new ways to use health care data to improve delivery of services. The conference, attended by data experts, entrepreneurs, technology developers and representatives of health care systems and communities has grown from a 45-person group who'd gathered 25 data sets five years ago to "more than 2,000 attendees, and thanks to leadership from HHS, local governments and state health departments … nearly 2,000 data sets available for them to explore and use in innovative ways," according to HHS Secretary Sylvia Mathews Burwell, in a statement on the HHS website. The data sets are accessible on HealthData.gov.

Besides the shift to value- rather than volume-based reimbursement, Burwell identified the next challenge as improving the organization and usage of health care information and data to help physicians in treatment decision-making and to encourage and enable patients to become more involved in their health care. Burwell solicited attendees' ideas on how to use data to better connect patients, physicians, and other providers and improve the health care system.

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Diagnostic Testing Plays Key Role in National Antibiotic Resistance Initiative

As we mentioned in our February issue covering the 2016 Budget, efforts to thwart antibiotic resistance are receiving substantial funding. That's because according to the Centers for Disease Control and Prevention (CDC), 2 million illnesses and 23,000 deaths annually can be linked to antibiotic resistance. The White House has established a Forum on Antibiotic Stewardship that brings together public and private entities across multiple industries to develop strategies to fight antibiotic resistance. With multiple legislative, public health and private initiatives working to solve the problem, laboratory diagnostics can play a central role in the fight.

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In addition to Secretary Burwell, other keynote addresses were provided by Esther Dyson, founder of HICCup, an organization seeking to build "Wellville" communities focused on helping people live healthier lives; Humana CEO Bruce Broussard; Dr. DJ Patil, Chief Data Scientist and Deputy Chief Technology Officer for Data Policy, White House Office of Science and Technology Policy; and Steven Brill, author of America's Bitter Pill: Money, Politics, Backroom Deals, and the Fight to Fix Our Broken Healthcare System.

"These data releases will give patients, researchers, and providers continued access to information to transform the health care delivery system."

— Andy Slavitt, acting CMS Administrator

Health Datapalooza also included panel discussions addressing issues such as changes in big data, transparency, the impact of health information on health care, and how health care businesses, state and local governments are using big data. Other sessions addressed point-of-care use of data, return on investment of health data, innovation, and the impact of health data use on patients and consumers. The event also included an exhibit hall, demos and wellness-focused activities such as a fun run and yoga sessions. Finally, post-conference workshops addressed: privacy, social media, creating an open data portal, the Office of the National Coordinator's Blue Button initiative (which enables patients to download and access their health care records online), and how to serve differing data users—such as researchers, policy makers, media, consumers and industry.

Physician and Hospital Medicare Payment Data Released

In the midst of this focus on data, the U.S. Department of Health and Human Services' Centers for Medicare and Medicaid Services (CMS) announced its annual release of utilization and payment data (third year for hospitals and second year for physicians and other professionals). This year's data relates to 2013 health care services.

"These data releases will give patients, researchers, and providers continued access to information to transform the health care delivery system," said acting CMS Administrator Andy Slavitt, in a press release announcing the data release. "It's important for consumers, their providers, researchers and other stakeholders to understand the delivery of care and spending under the Medicare program."

The physician/Part B data release shows payment and submitted charges for more than 950,000 providers, relating to $90 billion worth of Medicare payments. The information to be gained from the data allows comparison "by physician, specialty, location, types of medical services and procedures delivered," according to the CMS press release. For hospitals, the data compares hospital charges for services relating to the 100 most common reasons for hospitalization.

"Data transparency facilitates a vibrant health data ecosystem, promotes innovation, and leads to better informed and more engaged health care consumers," said Niall Brennan, CMS chief data officer and director of the Office of Enterprise and Data Analytics, in the release. Brennan also indicated CMS intends to continue with these annual data releases.

The data can be used to make geographic comparisons and detect trends, given the multiple years of data now available.

Access to Medicare Data for Researchers

During Datapalooza, Slavitt also announced that "innovators and entrepreneurs" will now have access to CMS data for research purposes. The data will not identify individual patients and research must be approved.

"Data is the essential ingredient to building a better, smarter, healthier system. Today's announcement is aimed directly at shaking up health care innovation and setting a new standard for data transparency," said Slavitt in a press release. "We expect a stream of new tools for beneficiaries and care providers that improve care and personalize decision-making."

Data will be accessible through the CMS Virtual Research Data Center (VRDC). Researchers can't remove the data from the system but they can "download aggregated, privacy-protected reports and results to their own personal workstation." Researchers can also request data quarterly, significantly increasing frequency from prior annual requests.

Part D Prescription Drug Data Publicized

While not directly relevant to laboratories, at the end of April, CMS also released data regarding prescriptions issued by physicians. That data release included information about prescribing patterns of over 1 million providers and related to over 3,000 drug products.

Takeaway: Transparency is not just a sound bite but a reality as CMS opens up access to Medicare-related health care information. G2

OIG Issues Fraud Alert Regarding Physician Compensation

The U.S. Department of Health and Human Services Office of Inspector General (OIG) has medical directorships and other physician compensation arrangements in its crosshairs. While not a novel issue, the OIG highlighted the kickback risks of such arrangements in a June 9, 2015 Fraud Alert, noting it has reached settlement with 12 physicians with regard to "questionable medical directorship and office staff arrangements."

"Although many compensation arrangements are legitimate, a compensation arrangement may violate the anti-kickback statute if even one purpose of the arrangement is to compensate a physician for his or her past or future referrals of Federal health care program business," said the Alert.

The OIG cautioned physicians to "carefully consider the terms and conditions of medical directorships and other compensation arrangements before entering them" and ensure they exchange fair market value compensation for bona fide services that the physician really does provide.

Factors and circumstances that the OIG found concerning in prior arrangements include:

- compensation that "took into account the physicians' volume or value of referrals"
- compensation greater than fair market value
- physicians failing to provide services as described in the agreement

- physician office staff salaries paid by affiliated entities (relieving the physician of that financial cost and thus benefitting the physician).

To avoid such compliance problems, the OIG suggested consulting the *Compliance Program Guidance for Individual and Small Group Physician Practices* and the OIG's *Roadmap for New Physicians: Avoiding Medicare and Medicaid Fraud and Abuse*, both of which are available on the OIG's website.

Typically, the arrangements at issue with medical directorships are those between hospitals and health systems and physicians that refer to the hospital. It's worth noting that another Fraud Alert issued in June last year, which directly addressed laboratories, also included a focus on payments to physicians. Further, the Biodiagnostic Laboratory Services case, which we have reported on multiple times, has involved criminal charges and even prison sentences for physicians who the government alleged had consulting and services arrangements with the laboratory. The government alleged payments under those arrangements were really kickbacks for referrals—which is the same risk this fraud alert highlights.

Takeaway: Payments by providers to physicians who are referral sources continue to be an enforcement target.

Mid-Year Update to OIG Work Plan Targets Laboratory Testing

Each year, the U.S. Department of Health and Human Services' Office of Inspector General's (OIG's) Work Plan highlights the projects and reviews it will pursue in the coming year. At the end of May, the OIG released an update adding new activities to that agenda. This latest update added one item directly addressing clinical laboratories.

That new item "Annual analysis of Medicare clinical laboratory payments" indicates the OIG plans to focus on Medicare payments for lab tests, "including the top 25 clinical diagnostic laboratory tests by Medicare expenditures in 2014" because its prior reviews revealed Medicare pays more than other payers "for certain high-volume and high-expenditure laboratory tests." Citing the Protecting Access to Medicare Act of 2014 (PAMA), the OIG says it will annually review and "monitor Medicare expenditures and the new payment system for laboratory tests."

Also of interest to laboratories is an item discussing electronic health records and coordination of care in Accountable Care Organizations (ACOs). The OIG says it will review ACO participants' use of electronic health records to share information while coordinating care and "identify best practices and possible challenges" as providers move toward interoperability. G2 Intelligence's report *Laboratory Services in Accountable Care Organizations* explains that achieving the "seamless" access to data of interoperability and "[t]o be able to collaborate and discuss diagnosis and treatment options, laboratories need to have easy access to clinical data stored in an EHR and clinicians need access to laboratory data stored in the LIS." The report cites interoperability as "one of the top two most significant challenges ACOs face in the deployment of HIT." G2 Intelligence surveys summarized in the report indicate ACO laboratories are taking action to improve data sharing and achieve interoperability.

Finally, the OIG also plans to take a close look at the "number and nature of financial interests" reported under the Open Payments program (also referred to as the Sunshine law). The OIG will be checking up on how the Centers for Medicare and Medicaid Services oversees the reporting of this data and whether the data is displayed in public databases.

The OIG's *Fiscal Year 2015 Work Plan Mid-Year Update* is available on the OIG Website under Reports and Publications.

Takeaway: Laboratories continue to attract scrutiny from the OIG and data continues to be a trending topic—both for the sake of transparency and compliance as well as for purposes of transforming health care delivery. G2

For further information or to obtain a copy of G2 Intelligence's report *Laboratory Services in Accountable Care Organizations*, please contact G2 customer service at 1-888-729-2315 or visit www.g2intelligence.com.

Enforcement for First Half of Fiscal 2015 to Yield $1.8 Billion in Recoveries

The U.S. Department of Health and Human Services Office of Inspector General (OIG) expects to recover more than $1.8 billion from its investigative and enforcement efforts during the first half of fiscal year 2015 (Oct. 2014 to March 2015), according to the OIG's semi-annual report to Congress.

That figure includes approximately $544.7 million attributable to audits and $1.26 billion due from investigative efforts. The OIG excluded 1,735 individuals from participating in federal health care programs and reported 422 criminal actions and 320 civil actions relating to health care compliance issues. The Health Care Fraud Prevention and Enforcement Action Team (HEAT)'s Medicare Strike Force enforcement yielded $163 million, charges against 69 individuals or entities, and 124 criminal actions. Medicare and Medicaid investigations included fraud relating to laboratory testing, according to the report, as well as prescription drugs, home health agencies, and durable medical equipment. For example, the report described a case resulting in a prison sentence and $246,536 in restitution for health care fraud involving an allergy testing laboratory that was alleged to have billed Medicare, Medicaid, TRICARE and private payers for blood sample allergy testing not actually performed. The OIG also reported another example regarding a chief financial officer of a medical center prosecuted for allegedly falsely attesting to electronic health records usage and meaningful use, to meet incentive requirements of the Electronic Health Records Incentive programs.

The OIG's efforts also uncovered inefficiencies in Medicare policies and practices that could "invite exploitation or hinder consistent payment determinations" and potentially improper payments. For example, the OIG noted hospice care to assisted living residents reached $2.1 billion in 2012 potentially indicating that hospices may be targeting beneficiaries in assisted living facilities because they yielded higher Medicare payments than other settings.

Takeaway: Fraud enforcement continues to be successful in gaining big recoveries and continues to include diagnostic testing as a productive target. G2

Researchers Call for Regulatory Oversight of Genomic Tests

Three researchers have suggested that the success of genomic testing depends on post-market data collection and analysis to help determine its safety and effectiveness. They further claim that Congressional action is needed to "incentivize the development of the massive data systems that doctors and regulators will need in order to make these tests safe and effective for patients." A Special Report by the researchers, based at the University of Washington School of Medicine and the University of Houston Law Center, was published in the May 27 on-line issue of the *New England Journal of Medicine*.

The authors say current regulatory oversight is insufficient and note that in the past Congress has acted when necessary to grant FDA additional authority. For example, the authors highlight enactment of the Food and Drug Administration Amendments Act (FDAAA), which the authors explain was in response to a need for post-market surveillance of drugs and "strengthened the power of the FDA to respond to emerging evidence" with labeling changes. The authors say the current device approval statute and regulations fall short of what's needed for genomic testing in part because it fails to require "ongoing, decades-long program of continuous learning to clarify both benefits and risks that are not yet known."

The law, bioethics and medical genetics researchers assert that genomic testing is still developing yet generates huge amounts of data and much is unknown about many of the variants it can detect. Further, they argue that existing genetic databases such as ClinVar, which the U.S. Food and Drug Administration proposed could be used to assess clinical validity, are insufficient and genomic data resources will need to be developed. "Whole-genome sequencing detects more than 3.5 million variants in a typical person, including 500,000 that are rare or novel. ClinVar, while it is an excellent data resource, currently only has about 77,000 unique genetic variants in it, and many of these are variants of unknown clinical significance," noted one of the report's authors, Wylie Burke, M.D., Ph.D., in the press release announcing the report.

The authors assert that data will need to be gathered from not just research but from commercial clinical laboratories performing tests for "large, diverse patient populations" and that developing these databases will be costly, requiring public and private funding. They conclude that the FDA doesn't have the authority under current medical device regulation to implement such data collection. Thus, they call for Congress to enact legislation that will:

- authorize development of a new genomic data system,
- enable public-private partnerships to fund the system, and
- enhance access to the data while protecting privacy.

The press release asserts that while the FDA's current powers need augmentation, "a relatively modest set of statutory reforms that builds on concepts the FDA already has developed for drugs and other medical devices could position the agency to play a crucial and constructive role." The authors conclude: "The stakes are high—high enough to warrant taking the time to get regulation right."

Takeaway: Debate about the right way to regulate genomic testing and the resources needed to do so continues. G2

Diagnostic Testing Plays Key Role in National Antibiotic Resistance Initiative, *Continued from bottom of p.1*

HHS' Initiatives

The U.S. Department of Health and Human Services (HHS) Secretary Sylvia Mathews Burwell and U.S. Department of Agriculture (USDA) Secretary Tom Vilsack highlighted efforts of their organizations in a recent HHS Blog post. HHS' Centers for Medicare and Medicaid Services (CMS) and the CDC will work to establish best practices for hospitals and other facilities and to track antibiotic use and resistance. The National Institutes of Health and the Biomedical Advanced Research and Development Authority are seeking public input on the parameters of a contest that would award up to $20 million (contingent on availability of funding) for development of point-of-care *in vitro* diagnostic tests that can be used to quickly identify bacterial infections, according to the HHS Blog post. A June 2 announcement of the public comment period regarding the contest indicates comments are due by July 17, 2015 and may address diagnostic performance, speed, cost, and technologies, among other topics.

Together, the CDC, USDA and U.S. Food and Drug Administration (FDA) expect to hold a summer 2015 public meeting to address antibiotic use and resistance in food-producing animals. The FDA has also proposed regulations regarding sales reporting requirements relating to antibiotics usage in food-producing animals and finalized requirements for use and oversight of antibiotics under the Veterinary Feed Directive.

The White House calls for better and faster testing to improve treatment decisionmaking.

White House Forum

A White House fact sheet announcing the White House Forum on Antibiotic Stewardship, said it would include over 150 entities from the food, retail, health care, and agricultural sectors. Participants commit to make changes over the next five years to "slow the emergence of resistant bacteria and prevent the spread of resistant infections." That announcement included emphasis on private sector efforts to help develop "new antibiotics, therapeutics, diagnostics, and vaccines." For example, Ascension Health's antimicrobial stewardship program will "evaluate facility antibiograms (the result of a laboratory test for the sensitivity of an isolated bacterial strain to different antibiotics)." Hospital Corporation of America is also committed to using "real time antibiogram tracking to rapidly respond to lab results, catch bug-drug mismatches" and avoid health care associated infections and report antibiotic resistance. The White House calls for better and faster testing to improve treatment decisionmaking. Participants BD Diagnostics and BioMerieux are listed as entities contributing to the effort. BD will be developing "rapid carbapenem-resistant Enterobacteriaceae diagnostic tests, new antibiotics to test antibiotic susceptibility testing platforms, and molecular multidrug resistant-tuberculosis diagnostic test to simultaneously test patients for bacteria and resistance, and pioneer new ways to examine and reduce C. difficile healthcare-associated infections." BioMerieux's efforts include work with the federal government "to ensure next-generation sequence-based typing of pathogens to track patterns; create high-medical-value multiplex assays combining host resistance markers, pathogen detection and antimicrobial resistance markers to rapidly diagnose (within approximately 1 hour) the cause of an infection to more accurately tailor empiric and definitive therapy; and validate biomarkers that can differentiate bacterial from viral infections in large cohorts to determine the best combination of markers in a single rapid diagnostic assay."

Other Efforts

Other current efforts in the fight against drug resistance include:

- Executive Order 13676 (Sept. 2014) addressing federal efforts to fight antibiotic resistance;
- A President's Council of Advisors on Science and Technology report recommending how to fight antibiotic resistant infections;
- National Action Plan for Combating Antibiotic-Resistant Bacteria—identifying federal efforts needed to "enhance diagnosis and treatment and limit the spread of antibiotic-resistant bacteria"; and
- A Presidential Memorandum promoting responsible use of antibiotics in meat and poultry.

Takeaway: Diagnostics play a pivotal role in coordinated federal efforts to fight antibiotic resistance. G2

Medicaid Managed Care Regulations Get Update

After more than a decade, Medicaid and the Children's Health Insurance Program (CHIP) managed care payment regulations are getting an update. The Centers for Medicare and Medicaid Services (CMS) announced a proposed rule in late May, addressing:

- beneficiary communication and access,
- program integrity and actuarial soundness requirements,
- quality and cost effective health care delivery, and
- alignment of Medicaid and CHIP managed care with other payer sources to ease patients' transitions between health care programs.

"A lot has changed in terms of best practices and the delivery of important health services in the managed care field over the last decade. This proposal will better align regulations and best practices to other health insurance programs, including the private market and Medicare Advantage plans, to strengthen federal and state efforts at providing quality, coordinated care to millions of Americans with Medicaid or CHIP insurance coverage," Acting CMS Administrator Andy Slavitt said in a press release announcing the proposal.

The proposed rule was published in the June 1, 2015 Federal Register. The deadline for public comments is July 27, 2015. CMS has also provided a Fact Sheet on its website summarizing the provisions of the proposed rule.

Takeaway: The government's focus on quality and cost-effectiveness continues with an update to Medicaid and CHIP managed care regulation to align policies and protect beneficiaries. G2

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Kelly A. Briganti, JD, Editorial Director, Kelly@plainlanguagemedia.com; Barbara Manning Grimm, Managing Editor; Stephanie Murg, Managing Director; Kim Punter, Director of Conferences & Events; Randy Cochran, Corporate Licensing Manager; Michael Sherman, Director of Marketing; Jim Pearmain, General Manager; Pete Stowe, Managing Partner; Mark T. Ziebarth, Publisher.
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