G2 INTELLIGENCE
A DIVISION OF PLAIN LANGUAGE MEDIA

NATIONAL INTELLIGENCE REPORT™

Covering Government Policy For Diagnostic Testing & Related Medical Services

Celebrating Our 39th Year of Publication

Vol. 18, Iss. 2/3, February/March 2018

INSIDE THIS ISSUE

Medicare Reimbursement: Federal Government Funding Extension Includes a Boatload of Medicare Changes

The government shutdown fiasco is having an impact on Medicare spending and reimbursement. But the crucial details are being buried in the legislative paperwork. So we decided to ferret them out for you.

The Continuing Resolution

On Feb. 6, 2018, the House passed a special kind of appropriations bill known as a Continuing Resolution (CR) to extend federal government funding until March 23. Among the CR's government-wide spending provisions are Medicare changes from other bills that passed the House or Senate. Here's an overview of the key changes.

Medicare Part B

The CR incorporates changes from the Medicare Part B Improvements Act, including:

Continued on page 2

Case of Month: Using Window Envelope to Mail HIV Info Costs Aetna $17+ Million

Talk about a mailroom mess-up! A shockingly bad choice in envelopes has just cost one of the country's largest health insurers over $17 million.

The Lawsuit

On Jan. 16, Aetna agreed to pay $17.2 million to settle a federal class action lawsuit by beneficiaries accusing the insurance giant of compromising their privacy by mailing them HIV medication information in an envelope with a transparent window. The July 2017 mailing which inadvertently revealed the patient's name, address and start of the letter, was sent to 12,000 beneficiaries taking medication for HIV, or PrEP, a pre-exposure prophylactic pill to prevent HIV. Ironically, Aetna sent the letter in response to beneficiaries whom had expressed earlier privacy concerns about having to obtain their HIV meds from mail-order pharmacies.

Continued on page 24

Medicare Reimbursement: Federal Government Funding Extension, *from page 1*

- Codification of recent CMS changes on when leases violate Stark Law regulations and when signatures are required to document terms of legal arrangements;
- Creation of temporary transition service and education Medicare payment for home infusion starting in 2019; and
- Green light for dialysis providers to seek outside accreditation from Medicare-approved organizations to qualify billing Medicare end-stage renal disease services.

Medicare Extenders

Key items in the CR provisions extending Medicare programs:

- Codification of new reporting and other requirements designed to ensure that beneficiaries get the diabetic testing supplies they need;
- Permanent repeal of Medicare payment cap for therapy services starting Jan. 1, 2018;
- Reduced threshold for targeted manual medical review process from $3,700 to $3,000;
- Permanent reauthorization of Medicare Advantage (MA) Special Needs Plans (SNPs) for vulnerable populations as well as revisions to Dual-Eligible SNPs and Chronic Condition SNPs;
- Five-year extension of 2% urban, 3% rural and 22.6% rural ground ambulance add-on payments through Dec. 31, 2022;
- Addition of providers and suppliers of ground ambulance as new category subject to annual cost reporting requirements;
- Two-year extension of funding for quality measure endorsement, input, selection and reporting requirements;
- Two-year straight extension of:
  - Geographic Cost Indices floor until Jan. 1, 2020;
  - Medicare-dependent hospital program until Oct. 1, 2019; and
  - Increased inpatient hospital payment adjustment for low-volume hospitals until Oct. 1, 2019;
- Five-year extension of home health rural add-on until Oct. 1, 2022, along with new methodology for targeting add-on payment to areas with population density of six or fewer people per square mile;
- Requirement that HHS Secretary reform the home health payment system and implement a 30-day episode for payment starting Jan. 1, 2020;
- Technical corrections to Quality Payment Program under MACRA, including changes to definition of "covered professional services" and giving CMS three more years to ensure gradual and incremental transition to performance threshold; and
- Making coverage of speech generating devices under medical equipment, which was due to expire in 2018, permanent.

NIR

Glenn S. Demby, Editor

Lori Solomon, Contributing Editor

Catherine Jones, Contributing Editor and Social Media Manager

Barbara Manning Grimm, Managing Editor

David van der Gulik, Designer

Randy Cochran, Corporate Licensing Manager

Myra Langsam, Business Development

Michael Sherman, Director of Marketing

Jim Pearmain, General Manager

Pete Stowe, Managing Partner

Mark T. Ziebarth, Publisher

National Intelligence Report (ISSN 2332-1466) is published by G2 Intelligence, Plain Language Media, LLLP, 15 Shaw Street, New London, CT, 06320.
Phone: 1-888-729-2315
Fax: 1-855-649-1623
Web site: www.G2Intelligence.com.

The CR includes provisions extending funding for public health programs.

CHRONIC Care Act

The CR includes changes affecting telehealth, MA plans and Accountable Care Organizations (ACOs) contained in the CHRONIC Care Act:

- Letting providers utilize telehealth for home dialysis patients;
- Letting MA plans offer a wider array of targeted supplemental benefits to chronically ill enrollees starting in 2020;
- Letting MA plans offer additional telehealth benefits in their annual bid amounts beyond the services that currently receive payment under Part B starting in 2020;
- Letting ACOs expand their use of telehealth services;
- Expanding use of telehealth for stroke patients starting in 2021;
- Giving Medicare ACOs the option to have their beneficiaries assigned prospectively at start of a performance year and beneficiaries the option to voluntarily align to an ACO in which the beneficiary's main primary care provider participates; and
- Creating new voluntary ACO Beneficiary Incentive Program letting two-sided risk ACOs make incentive payments to all assigned beneficiaries who receive qualifying primary care services.

Public Health

The CR includes provisions extending funding for public health programs:

- Two years of funding for community health centers;
- Two years of funding for the National Health Service Corps and Teaching Health Center;
- Two years of funding for the Special Diabetes Program for Type 1 Diabetes and the Special Diabetes Program for Indians;

Cuts to Finance Spending Increases

The CR lists specific health-related fiscal offsets to finance the above spending enhancements, including:

- Modified payments for early discharges to hospice care;
- Cuts in pay for non-emergency ambulance transports of kidney patients;
- Extending the target for relative value adjustment for mis-valued codes for one more year;
- Delaying CMS's authority to terminate contracts for certain MA plans through the 10-year budget window;
- Rescinding unspent money from the Medicare and Medicaid Improvement Funds;
- Cutting pay for outpatient physical and occupational therapy services by a therapy assistant to 85% of the rate that would have otherwise been paid for by a physician;
- Reducing long term care hospital (LTCH) payments by delaying the

current law blended payment rate for two years and reverting back to the FY17 blended rate of 50% site neutral and 50% LTCH;

- Reducing the LTCH market basket update for FY18 through FY26 by 4.6%;
- Changes to Medicaid and CHIP's third-party liability requirements;
- Requiring state Medicaid programs to count lottery winnings for determining an individual's income eligibility under Medicaid;
- Eliminating the Medicaid Disproportionate Share Hospital (DSH) reductions scheduled for FY18 and FY19 under current law;
- Requiring $6 billion in additional DSH reductions to offset the cost of eliminating the FY18 and FY19 reductions—$3 billion in FY21; $2 billion in FY22; and $1 billion in FY23;
- Setting the FY20 market basket update for home health agencies at 1.4%; and
- Includes biosimilars in the Medicare Part D coverage gap discount program.

Takeaway: Few, if any, of these spending changes will have a direct impact on labs—especially those whose involvement with Medicare is limited to billing for lab tests under Part B. By the same token, the changes may have major, albeit indirect, effects on some labs, particularly those affiliated with hospitals and integrated health care organizations.

Anti-Kickback Statute: OIG Eyes Changes to Safe Harbor Rules

As it does every year, the OIG is reviewing the federal Anti-Kickback Statute (AKS) current safe harbor rules. The deadline to comment: end of business, Feb. 26. Here's a quick rundown of what's at stake.

The AKS

The AKS makes it a criminal offense for labs and other providers to offer or pay "remuneration" to physicians for Medicare/Medicaid/TRICARE and other federal health program referrals. The term "remuneration" is interpreted broadly to include not just money but also non-cash benefits such as gifts, supplies and services offered for free or at less than their fair market value. Penalties for AKS violations include fines of up to $25K + three times the remuneration amount, civil monetary penalties and imprisonment of up to five years. AKS violations can also result in liability under other federal laws including the False Claims Act and Stark Law.

The Safe Harbors

Because the AKS is so broad, many of the common business arrangements that labs make with their referring physicians raise potential AKS liability concerns to the extent the value physicians derive from the deal is deemed illegal "remuneration." The good news is that the AKS and its regulations

The OIG is required to review the safe harbor rules each year to ensure that they are in line with current legislation, technology and business practices.

carve out "safe harbors" allowing for otherwise problematic transactions provided that the anti-abuse precautions prescribed by the safe harbor are met. Although safe harbors are not mandatory, following them provides the parties a degree of comfort that they won't get into trouble for doing the deal.

In fact, without safe harbors, it would be almost impossible for labs, hospitals and other providers to conduct business with referral sources. Key safe harbors affecting labs and referring physicians include provisions making allowances for:

- Bona fide employment relationships;
- Personal services and management contracts;
- Discounts; and
- Fair market value space or equipment rentals.

The OIG Review

The OIG is required to review the safe harbor rules each year to ensure that they are in line with current legislation, technology and business practices. The law also lists specific criteria for adopting new safe harbors or revising old ones, including the extent to which the proposed change would affect:

- Access to health care services;
- Quality of care;
- Patient freedom of choice in selecting providers;
- Competition among providers;
- Costs to federal health care programs;
- Potential overutilization; and
- The ability of health care facilities to serve medically underserved areas or populations.

The OIG also considers whether arrangements provide potential financial benefits that may affect a provider's treatment decision—in the lab context, e.g., what lab tests to order and from which lab to order them.

Special Fraud Alerts

The current OIG review also addresses when and how the agency should issue new Special Fraud Alerts to warn providers of business practices it considers suspicious and explaining what providers should do to allay those concerns. OIG Special Fraud Alerts, which are published in the Federal Register, have become fewer and farther between in recent years.

Takeaway: Based on recent OIG safe harbor activity (see the related story on page 6) and the current administration's pronounced proclivity for cutting regulation, it is a pretty good bet that the current review will result in changes that expand safe harbor protection and economic leeway for deal making between labs, hospitals and other providers and their referral sources.

Enforcement Trends: The OIG's Recent Safe Harbor Changes

On Feb. 26, the OIG will wrap up public comments on changes to the federal Anti-Kickback Statute (AKS) current safe harbor rules. While such review takes place every year, 2018 could be a year of big changes designed to expand safe harbor protection and promote more active deal making between providers and their referral sources.

While the current political mandate to cut regulation is one factor, the OIG's efforts to loosen AKS restrictions actually date back to the previous administration. Exhibit A: The Safe Harbor and Civil Monetary Penalty (CMP) Revisions Final Rule that took effect on Dec. 7, 2016, six weeks before the current President was sworn in. Here's a quick overview of the five changes affecting labs.

1. New Free Transportation Safe Harbor

The change with the most direct impact on labs was the new safe harbor covering "free or discounted local transportation services provided to" federal program beneficiaries. The new safe harbor covers both:

- Actual transportation to and from a patient's home so as to provide the patient access to a provider or supplier; and
- Transportation vouchers.

Of course, safe harbors always come with strings attached. Key limitations of the new safe harbor:

- Transportation may only be offered to established patients, which is defined as including new patients who contact the provider to schedule an appointment—once the initial appointment is made, those patients are deemed established patients;
- It covers only certain types of transportation, including luxury, air and ambulance level service;
- The lab may not advertise or use as a marketing tool the fact that it provides free or discounted transportation;
- Health care services or items may not be advertised or marketed during the transportation or at any time by drivers;
- Drivers and others involved in arranging the transportation may not be compensated on a "per-beneficiary-transported basis";
- Transportation must be for the purpose of accessing medically necessary items and services;
- The entity making the transport possible must bear the cost of transport and may not shift those costs to federal programs or other payers or individuals; and
- The maximum distance of transportation to the lab is 25 miles in urban areas and 50 miles in rural areas, measured "as the crow flies" within a radius of that mileage.

It is important to stress that the OIG was considering excluding lab and home health services from the safe harbor due to concerns that transportation offered by these providers would be more likely to induce referrals. But

after soliciting comments, the OIG ultimately decided not to omit labs and home health providers from the Final Rule.

2. Technical Correction to "Referral Services" Safe Harbor

One current AKS safe harbor allows participants to make payments to a referral service as long as the payment is:

- Assessed equally against and collected equally from all participants, e.g., not just Medicare participants; and
- Based solely on the costs of operating the referral service and not on the volume or value of referrals to or business generated "by either party for the referral service" for which payment may be made under Medicare.

The Final Rule makes a technical change by eliminating the phrase "by either party for the referral service" and substituting "by either party for the other party." The change was made to eliminate the ambiguity in the current language that could be interpreted as meaning referral services may adjust their fees on the basis of volumes of referrals made to participants, the OIG explains.

3. New Safe Harbor for Pharmacy Cost-Sharing Waivers

A new safe harbors allows providers to waive or reduce Medicare/Medicaid beneficiary coinsurance/deductible amounts, including waivers or reductions by pharmacies of cost-sharing obligations under Medicare Part D and other federal health care programs, e.g., physician copayments for Part B drugs, as long as:

- The waiver/reduction is not advertised or used for marketing;
- The pharmacy does not routinely waive cost-sharing; and
- The pharmacy either:
  - Determines in good faith that the beneficiary has a financial need; or
  - Fails to collect cost-sharing amounts after making reasonable efforts to do so.

4. New Safe Harbor for Emergency Ambulance Cost-Sharing Waivers

Another new safe harbor permits waiver or reduction Medicare/Medicaid beneficiary coinsurance/deductible amounts for "emergency ambulance services" furnished by a Part B ambulance provider or supplier owned or operated by a state or its political subdivision (or a tribal health program), provided that:

- Providers offer the waiver or reduction on a uniform basis;
- Waivers and reductions are not based on patient-specific factors other than residency; and
- Providers do not claim the waiver or deduction amount as bad debt.

5. Revisions to "Nominal Value" Thresholds

On the same day the Final Rule was published, the OIG issued a new Policy Statement adjusting its thresholds for "nominal value," i.e., gifts or items that do not constitute "remuneration" banned by the AKS because their value is so low:

- Previous thresholds: $10 per item and $50 in the aggregate (per patient per year);
- Updated thresholds: $15 per item and $75 in the aggregate.

Labs IN COURT

A roundup of recent cases and enforcement actions involving the diagnostics industry

HDL, Part II: Time to Hold the Individual Officers Accountable

Case: Three years after Health Diagnostics Laboratory, Inc. (HDL) and its marketing partner BlueWave Healthcare Consultants—both now defunct—paid the feds $50 million to settle kickback claims, the individuals involved in the scheme have been brought to justice. On Jan. 31, a federal jury in South Carolina unanimously convicted HDL's former CEO and BlueWave's two co-owners of conspiring to pay doctors sham specimen processing and handling fees of $17 and routinely waiving copays and deductibles in exchange for referring Medicare and Tricare to HDL and its partner Singulex for medically unnecessary blood testing. But the $16 million damage award the jury returned was far below the $174 million the DOJ asked for.

Significance: For sheer dimensions, the HDL scheme has been described as among, if not the biggest case of lab fraud ever. In many ways, it also represents the new dynamic of federal healthcare fraud enforcement, not simply because it began as a whistleblower suit (actually, a series of three suits) but in its following of Yates Memo principles of separating the corporation from its individual principals and going after each group separately. This strategy represents a dramatic departure from previous DOJ policy of focusing on the corporate entity and allowing the individuals to avail themselves of the corporate liability shield and legal defense.

Illumina Wins $26.7 Million in Patent Infringement Damages

Case: Illumina won a patent infringement lawsuit against Ariosa Diagnostics in the US District Court of the Northern District of California. The case began in 2014 when Illumina claimed that Ariosa's test for "simultaneous quantification of hundreds of DNA loci" infringed the former's patent covering methods for amplifying and genotyping samples simultaneously. That same year, Roche acquired Ariosa and created a microarray version of the test. So Illumina filed a second suit claiming that the new test also infringed. The jury agreed with both claims and awarded Illumina $26.7 million in damages.

Significance: The case may not be over. General counsel for Roche Molecular Solutions is quoted as saying in an email that the company is disappointed" with the decision and is reviewing its legal options. Stay tuned.

Fresenius Settles HIPAA ePHI Charges for $3.5 Million

Case: HIPAA requires providers to perform a thorough risk assessment of the systems they use to secure electronic personal health information (ePHI) and correct the vulnerabilities they identify. On Feb. 1, the federal agency that enforces the HIPAA rules, the HHS Office for Civil Rights, announced that Fresenius Medical Care North America has agreed to fork over $3.5 million to settle charges of failing to meet this obligation at five of its facilities. The specific forms of violation varied from facility to facility—lack of procedures for incident response, no policies for removing hardware and electronic media containing ePHI within and outside the facility, inadequate encryption, failure to prevent unauthorized access, etc.

Significance: Although the $3.5 million fine stings, the real pain point for Fresenius may be the onerous corrective action plan that OCR imposed on the affected facilities, including the obligation to:

- Conduct a top-to-bottom HIPAA compliance audits;
- Submit a Risk Management Plan based on the audit findings to HHS for approval;

- Submit separate written reports on encryption measures and device and media controls;
- Develop and implement an enhanced privacy and security awareness training program; and
- Deliver annual reports and training reports.

Allergy Firm Claims Quest Conspired to Freeze It Out of the Market

Case: Texas-based United Allergy Services (UAS) is suing Quest Diagnostics for conspiring with Thermo Fisher Scientific's Phadia business and other market players to squeeze it out of the market in a deliberate bid to eliminate lower-priced competition. The suit claims that Quest and its co-conspirators persuaded insurers and other potential customers that doing business with UAS would create "medical, legal and other risks." UAS, which provides testing and allergen immunotherapy for hay fever and other allergies, claims it lost $200 million in profits as a result of the plot.

Significance: There's a mysterious subtext. The case actually began in 2014, when UAS sued Quest's co-conspirators but not Quest. Why UAS decided to bring a separate subsequent action against the lab giant rather than naming it in the original suit is unclear. In any event, that original suit has now been dismissed. Meanwhile the plot thickens, as UAS deals with a whistleblower lawsuit by a former marketing representative accusing it of overbilling Medicare for allergy testing. It adds up to a fascinating drama and we'll keep you apprised as it unfolds.

Venture Capital Investment in Diagnostic Companies Strong in 2017

Venture capital investments in health care innovation reached an all time high in 2017, including in diagnostics/tools (Dx/Tools) companies, according to Silicon Valley Banks' preliminary *2018 Healthcare Investments and Exits Report*. Investment was strong in Dx/Tools companies, particularly in companies using artificial intelligence, informatics, and liquid biopsy technologies.

"As Dx/Tools companies integrate computational methods such as artificial intelligence, we see tech investors, many new to health care, starting to invest in these deals," writes lead author of the report Jonathan Norris, managing director at Silicon Valley Bank.

In total, U.S. health care venture fundraising reached a record $9.1 billion, a 26 percent increase over 2016. The previous record was $7.5 billion raised in 2015. Dx/Tools fundraising increased 40 percent, reaching $2.8 billion in 2017. However, 60 percent of this total—or $1.6 billion—came from investments in liquid biopsy companies Guardant Health (Redwood City, Calif.) and GRAIL (Menlo, Park, Calif.), an Illumina spin off.

AI, Liquid Biopsy Led Dx/Tools Investments

- In total, 19 Dx Test companies received more than $2 billion in investment.
- Large investments were also made in the DX Analytics space with 16 companies receiving a combined $749 million, including 23andMe

(Mountain View, Calif.), WuXiNextCode (Cambridge, Mass.), Color (South San Francisco, Calif.), and AccuraGen (Menlo Park, Calif.).

- The Dx/Tools subset that Silicon Bank calls R&D Tools, defined as research equipment and services for biopharma and academia, closed 42 deals valued at $981 million in 2017, up 50 percent since 2016. These investments benefited the analytics platform company Human Longevity (San Diego, Calif.) and liquid biopsy tools makers Quanterix (Lexington, Mass.) and RareCyte (Seattle, Wash.).
- Liquid biopsy investment "exploded" with $1.8 billion (85 percent of the total raised) in Guardant Health, Grail, and Human Longevity.

Early-Stage Investments Are Smaller

In contrast to previous years, series A investments were made in early-stage Dx companies. Overall, the Dx/Tools sector saw an increase in the number of series A investments (73 in 2017 versus 55 in 2016). However, the value of investments fell slightly from $516 million 2016 to %500 million in 2017. This caused the median round size to also drop from $5.3 million in 2016 to $4.7 million in 2017.

- The R&D Tools subset had four series A investments at $25 million or more. Norris attributes this interest in R&D Tools companies to the lack of regulatory and reimbursement hurdles facing other Dx/Tools subsectors.
- However, the majority of deals valued at $10 million or more were companies using artificial intelligence, like PathAI (Cambridge, Mass.) and M2Gen (Tampa, Fla.).

Dx/Tools Companies Lacking Exits in 2017

Dx/Tools had no big mergers and acquisitions in 2017 and only one initial public offering. Given the strength of investments in Dx/Tools, Norris does anticipate big exits in the sector in the next few years. This, he says, will be driven by two factors tech giants who have been making investments in the sector will also emerge as potential acquirers.

"We anticipate that tech-focused investors will continue to apply their software expertise in Dx Analytics deals that leverage artificial intelligence," explains Norris. "While tech corporate venture participation has increased, these investors focus on a small set of deals most compatible with their own technologies."

2018 Predictions

Overall, Norris expects a slight pullback in health innovation-related investment in 2018, predicting that fundraising will "be strong," but will decline to below $7 billion in 2018. In line with this, Dx/Tool investments will also decline. However, the decline may appear dramatic, as the 2017 numbers were substantially boosted by large investment in just a few deals, namely GRAIL. Despite the anticipated decline in the value of investment, Norris, expects the number of Dx/Tool deals to remain "steady" in 2018.

Takeaway: the Dx/Tools sector saw strong venture capital investment in 2017, driven in large part by huge interest in artificial intelligence-based analytics and liquid biopsy technology

FOCUS ON: SEXUAL HARASSMENT

5 Common Sexual Harassment Policy Blind Spots & How to Fix Them

Recent weeks have witnessed the morphing of workplace sexual harassment prevention from legal requirement to moral imperative. And while the current fervor is a bit unnerving for employers, to the extent it shatters complacency, it's a positive and even necessary development. Sexual harassment has evolved dramatically in the past two decades—in terms of not just conduct but our understanding of it.

As a result, the traditional sexual harassment policy, of circa 2000, has become out of date and badly in need of revision. So reviewing your lab's current sexual harassment policy is not only a justifiable use of time but an imperative. Here are five common blind spots to look for in your review.

Ban sexual harassment not just "in the workplace" or "the lab" but all work-related settings, including offsite activities.

1. Banning Sexual Harassment "in the Workplace"

Blind Spot: Typical policies ban sexual harassment "in the workplace." The problem is that sexual harassment occurs not just within the four corners of the physical workplace but also offsite—in vehicles, during business trips and even at home. Moreover, the employer's duty to prevent sexual harassment may follow employees wherever they go in the course of their job duties, especially when they are in the company of co-workers.

Examples:

- California court refuses to dismiss sexual harassment claim of employee/actor who was allegedly drugged and gang raped at home of co-worker/casting director;
- Male salesman's inappropriate sexual remarks to female co-worker at bar was sexual harassment even though it occurred away from work site;
- Failure to take action in response to employee's complaints about co-worker's harassing phone calls makes employer liable for creating hostile work environment even though calls were made from (and to) home after work hours.

How to Fix It: Ban sexual harassment not just "in the workplace" or "the lab" but all work-related settings, including offsite activities such as:

- Client and customer visits and service calls;
- Business travel;
- Conferences, training sessions and seminars;
- Company or client-sponsored social functions;
- Any other offsite work assignments.

FOCUS ON: SEXUAL HARASSMENT

2. Banning Sexual Harassment "by Co-Workers, Supervisors and Managers"

Blind Spot: As with setting, sexual harassment is personnel-agnostic. Employees can suffer it at the hands of not just individuals who work for the same organization but third parties like customers, clients and even outside service personnel.

Example: During a service visit, a photocopy technician smacks an employee on the butt with a rolled up newspaper as she bends over to pick up a fallen ink cartridge. The victim's employer is found liable for sexual harassment even though the technician is an employee of the service company and not the organization.

Old-school sexual harassment policies don't deal with what is rapidly becoming the face of sexual harassment in the 21st century: cyber bullying and revenge porn.

How to Fix It: Your commitment to protect lab employees from sexual harassment should extend to harassment from third parties that employees may encounter in the course of their job at least to the extent you have a reasonable degree of control over those parties, e.g., customers, clients, vendors and contract personnel. While it may be admirable in principle, seeking to extend this commitment to *all* third parties is neither reasonable nor realistic.

3. Omission of Cyber Harassment & Revenge Porn

Blind Spot: Old-school sexual harassment policies don't deal with what is rapidly becoming the face of sexual harassment in the 21st century: cyber bullying and revenge porn. The latter refers to vindictive and nonconsensual online posting of nude or sexually explicit photos, videos and other depictions of ex-lovers in an attempt to embarrass, humiliate and ruin lives. And it frequently happens in the workplace. Although the law is still evolving, the early cases indicate that it's only a matter of time before the employer's sexual harassment duties are extended to cyber bullying and revenge porn.

How to Fix It: Make sure your policy defines sexual harassment to include cyber bullying and stalking, non-consensual taking or posting of sexual activity and other forms of sexual abuse against co-workers via social media and other digital fora.

4. Omission of Other Forms of Sexual Misconduct

Blind Spot: While sexual harassment is the most common, it's not the *only* form of workplace sexual misconduct. And while using the term "sexual harassment" to refer to the whole enchilada may be clear enough for everyday parlance, it won't work in the context of an HR policy.

How to Fix It: Ban not just "sexual harassment" but all forms of sexual misconduct that employees may suffer in the course of their work, including:

FOCUS ON: SEXUAL HARASSMENT

- Non-consensual sexual contact or attempts to commit it (just be sure to include a clear definition of "consent");
- Dating violence or abuse, i.e., use of fear, degradation, humiliation and/or abuse against a dating partner to gain power and control in the relationship;
- Domestic violence;
- Stalking and cyber stalking;
- Sexually-based communication, i.e., in-person, phone, social media, electronic messages and other communications of a sexual nature that are unwelcome to the employee recipient;
- Invasion of an employee's sexual privacy;
- Exceeding the limits of consent, e.g., Bob lets a friend hide in the closet so he can watch Bob have consensual sex with his co-worker;
- Knowingly transmitting a sexual infection or disease to another person;
- Non-consensual sexual exposure.

5. Lack of Accountability for Bad Faith Accusations

Blind Spot: While most sexual harassment complaints are made in good faith, there's always the risk of employees' of abusing the system by making accusations they know to be baseless. Most sexual harassment policies aren't equipped to deal with these abuses.

- *Pattern 1:* The policy doesn't hold employees accountable for such abuses; or
- *Pattern 2:* The policy holds employees accountable for "false" accusations.

The first policy doesn't go far enough; and the second policy goes too far. Punishing employees for making "false" sexual harassment complaints exposes you to liability risks for retaliation if the employee made the accusation in good faith and sincerely believed he/she was harassed.

How to Fix It: Reserve the right to punish not false but bad faith complaints. Specify that you won't consider a complaint to be in bad faith merely because the evidence doesn't ultimately support the accusation and that bad faith requires a finding that the complaining employee acted maliciously either knowing that the accusation was false or recklessly without regard to whether the accusation was true.

Takeaway: The old-school sexual harassment policy, circa 2000, has become obsolete and needs to be revised to comport with modern times, technology, wisdom and understanding about how sexual harassment occurs.

FOCUS ON: SEXUAL HARASSMENT

The sexual harassment policy has been a fixture of the HR manual for decades. And that's the problem. While lack of toleration for sexual harassment is decades-old, the conduct and our understanding of how to deal with it has evolved significantly in recent years. In the current environment, reviewing your current sexual harassment policy is not only a justifiable use of time but an imperative. Here's a Model Sexual Harassment Policy template you can use to conduct your review.

LABORATORY SEXUAL HARASSMENT POLICY

1. LABORATORY COMMITMENT & PRINCIPLES

XYZ Laboratory (Laboratory) is fully committed to providing employees a work environment that is positive, respectful and safe, one that recognizes, respects and embraces the individual dignity, worth and rights of all our employees regardless of gender. We will not tolerate sexual harassment in any form and we are committed to taking all complaints of such conduct seriously and responding as quickly as possible and holding individuals found to have engaged in such conduct fully accountable regardless of position.

2. PURPOSE

The purpose of this Policy is twofold:

a. To establish clear ground rules regarding sexual harassment and other forms of sexual misconduct so that all employees understand what is and is not acceptable and can thus behave accordingly; and

b. To describe the procedures that XYZ Laboratory follows for receiving, investigating and responding to complaints of sexual harassment, including imposition of discipline for those found guilty of offenses.

3. DEFINITION OF SEXUAL HARASSMENT

For the purposes of this Policy, sexual harassment in the workplace refers to a course of offensive, humiliating or intimidating comment or behavior based on sex or gender (typically but not exclusively by one employee—which may include a supervisor or manager) against another, that the person engaging in the behavior knows or ought reasonably to know is unwelcome. Sexual harassment negatively affects the work environment and can lead to negative work-related consequences for the victim. Sexual harassment may consist of a single incident of unwelcome behavior or multiple incidents over time. Sexual harassment is also form of discrimination that is prohibited under both federal and state discrimination laws.

3.1. What Constitutes Sexual Harassment

Sexual harassment includes, but is not limited to:

Physical Harassment. Examples:

- Leering or inappropriate staring;
- Invasion of personal space;
- Unwelcome and unnecessary physical contact (touching, grabbing, hugging, kissing, etc.);
- Sexual assault and violence.

Verbal Harassment. Examples:

- Making offensive comments or engaging in behavior towards a person based on their gender, gender identity, gender expression and/or sexual orientation;
- Making sex-related comments about a person's physical appearance or actions;
- Making comments or engaging in behavior because of a belief that someone does not conform to gender-role stereotypes;

FOCUS ON: SEXUAL HARASSMENT

- Making offensive comments about members of a specific gender or sexual orientation;
- Using vulgar, sexual or gender-related humor or derogatory language (such as slurs, jokes or innuendo);
- Asking unwelcome questions or engaging in unwelcome conversation about sexual activities;
- Spreading sexual rumors (including online).

Hostile Work Environment Harassment. Examples:

- Displaying or distributing pornographic or other sexual images, objects, jokes or sayings (including online);
- Making vulgar gestures.

Threats and Demands. Examples:

- Asking for sexual favors in exchange for workplace benefits;
- Repeatedly asking someone for dates or sexual favors even after they have said no;
- Threatening someone (e.g., with violence, termination or denial of other workplace benefits) if they refuse to comply with sexual advances;
- Making an employee dress or behave in a sexualized or gender-specific way;
- Threats of retaliation or reprisal if the victim makes a complaint under this Policy or exercises his/her recourse under employment discrimination or other laws.

3.2. Where Sexual Harassment Can Take Place

For the purposes of this Policy, the workplace or work environment refers to all workplace-related activities, including:

- Activities on Laboratory premises;
- Work assignments outside of Laboratory premises ;
- Work-related conferences, training sessions, or seminars;
- Work-related travel;
- Work-related social functions that Laboratory or its clients or associates sponsor or organize.

The above scope of activities in which sexual harassment can occur includes the job application and interview process, volunteer work and internships with Laboratory, and activities or events that take place outside regular business hours or locations but are linked to and may impact the workplace environment.

This Policy applies to all permanent and temporary employees at all levels, to those with whom Laboratory conducts business, and at all sites where Laboratory business activities take place.

3.3. Potential Victims of Sexual Harassment

Both women and men may engage in and experience sexual harassment in the workplace, but women are generally more vulnerable to it because they often hold jobs with lower pay, authority and status than men. That being said, even women in positions of authority can experience sexual harassment. Treating and portraying an employee, especially a woman, in a sexual way can undermine their status and image in the eyes of their co-workers.

In addition, sexual harassment can be perpetrated by women targeting men and by men or women targeting members of their own sex or gender. The offense is defined not by the gender of the victim and victimizer but the sexual nature of the conduct.

3.4. What Does NOT Constitute Sexual Harassment

The definition of sexual harassment and the Laboratory Sexual Harassment Policy are not intended to inhibit interactions based on mutual consent between employees, such as consensual conversation about sex in the workplace, or suggestive imagery, like a poster, that does not offend anyone. However, if you are offended by comments or imagery in the workplace even when no one else is, this does not mean that your concern is invalid. You should express your objections to those involved and file a complaint if the issue is not resolved.

FOCUS ON: SEXUAL HARASSMENT

4. OTHER FORMS OF PROHIBITED SEXUAL MISCONDUCT

4.1. Sexual Offenses Other than Harassment

Laboratory is committed to preventing and protecting employees against not just sexual harassment but a wide range of behaviors and conduct of a sexual nature that is nonconsensual or has the purpose or effect of threatening, intimidating or coercing. As with harassment, both men and women may be perpetrators as well as victims of sexual misconduct.

4.2. Definition of Consent

For the purposes of this Policy, consent means conscious, informed, fully voluntary agreement to, or permission for, an act. In determining whether consent has been given, the following principles will apply:

- Although consent may be implied verbally or nonverbally, it should never be assumed;
- Silence, inaction or absence of express denial of consent do not necessarily imply consent;
- Consent is valid only if it is given voluntarily without threat, force or duress;
- Consent is valid only if it is given by a person with adequate capacity—valid consent cannot be provided by a person who is asleep, drunk, high, physically or mentally incapacitated or otherwise judgment-impaired;
- Consent is not valid if it is provided by a person under the legal age of consent;
- Consent is limited in scope—consenting to one form of sexual activity is not implied consent to another form of sexual activity;
- Consent can be taken back at any time.

4.3. Forms of Prohibited Sexual Misconduct

Forms of sexual misconduct banned by this Policy include, but are not limited to:

a. NonConsensual Sexual Contact (or Attempts to Commit It), i.e., any intentional sexual touching, however slight, with any object by a person upon a person without consent and/or by force, including (without limitation):

- Contact with the breasts, buttocks, groin or genitals;
- Making another person touch the abuser, victim or a third party with or on any of those body parts; and/or
- Any other intentional bodily contact in a sexual manner not involving contact with/of/by breasts, buttocks, groin, genitals, mouth or other orifice.

b. NonConsensual Sexual Intercourse (or Attempts to Commit It), i.e., any sexual intercourse, however slight, with any object by a person upon a person without consent and/or by force, including (without limitation):

- Vaginal penetration by a penis, object, tongue or finger;
- Anal penetration by a penis, object, tongue, or finger, and/or
- Oral copulation (mouth-to-genital contact or genital-to-mouth contact).

c. Dating Violence, i.e., a pattern of assaultive and controlling behaviors by a person against a dating partner in an attempt to use fear, degradation, humiliation and/or abuse to gain or maintain power and control in the relationship.

d. Domestic Violence, i.e., use of physical, sexual or emotional abuse or threats to control a current or former spouse or other intimate partner, e.g., a person with whom the abuser is living or has lived with in the past.

e. Stalking, i.e., a pattern of repeated and unwanted attention, harassment, contact or other course of conduct directed at a specific person which would cause a reasonable person to become alarmed or fear harm or injury, including physical, emotional or psychological harm.

f. Cyber-Stalking, i.e., use of electronic media such as the internet, social networks, blogs, cell phones,

FOCUS ON: SEXUAL HARASSMENT

texts or other similar devices or forms of contact to pursue, harass or make unwelcome contact with another person.

g. Sexual Exploitation, i.e., taking sexual advantage of another person for the advantage or benefit of the person committing the exploitation or a third person to the extent such behavior does not constitute sexual harassment or one of the other forms of sexual misconduct banned by this Policy. Examples:

- Invasion of sexual privacy;
- Prostituting another person;
- Photographing, video-or audio-taping sexual activity without consent;
- Exceeding the boundaries of consent, e.g., letting a friend hide in the closet so he can watch you have consensual sex with your partner;
- Voyeurism;
- Knowingly transmitting a sexually transmitted infection, disease or HIV to another person;
- Non-consensual exposure of genitals; and
- Sexually-based stalking.

h. Sexually-Based Communication, i.e., speaking to, or directing any kind of communication, words or images of a sexual nature at another person which is not welcomed by the receiving party, which may include interactions in person, by phone, social media, electronic messages and photos and written words or images such as graffiti.

5. ROLES & RESPONSIBILITIES

5.1. Duty of Management

Laboratory management is committed to:

- Treating all co-workers, seniors, subordinates, colleagues and others with whom they interact with professionalism, dignity and respect in adherence to this Policy;
- Providing satisfactory resources to deal with sexual harassment complaints;
- Taking complaints seriously and responding quickly; and
- Fostering a healthy environment where employees feel comfortable about raising complaints and are kept informed about and involved with actions taken in response.

5.2. Duty of Supervisors

Supervisors will:

- Treat all co-workers, seniors, subordinates, colleagues and others with whom they interact with professionalism, dignity and respect in adherence to this Policy;
- Ensure that all employees, including those in positions of responsibility, are made aware of sexual harassment policies as soon as they are introduced, as well as through training, orientation material and education on human rights issues; and
- Continually monitor the work environment to make sure it is free from sexually harassing behavior.

5.3. Duty of Workers

Workers will:

- Treat all co-workers, seniors, subordinates, colleagues and others with whom they interact with professionalism, dignity and respect in adherence to this Policy;
- Immediately notify a supervisor or manager if they experience or witness incidents of sexual harassment or other violations of this Policy.

6. REPORTING SEXUAL HARASSMENT & MISCONDUCT

6.1. Procedures

Laboratory wants to ensure all its employees feel safe, comfortable and encouraged to report any incident of sexual harassment or misconduct they have observed or experienced. Please file a complaint about any incident to your manager [*contact name and info*] or HR advisor [*contact name and*

FOCUS ON: SEXUAL HARASSMENT

info]. If it is not appropriate to file a complaint with these individuals because they are involved in the incident, the employee should report the incident to any other manager of their choice.

Complaints need not be in writing but should include as much detail as possible, including the name(s) of the individual(s) involved and a description of the incident(s), including actions and/or comments made, place(s), date(s) and time(s).

The possibility of informal resolution may be explored and reached with the consent of all parties. If no informal resolution is sufficient, a formal and thorough investigation of the incident and surrounding circumstances will be undertaken, involving interviews with the complainant, the respondent, and any other individuals who may be able to provide information on the situation.

If the process within the workplace does not address or resolve the issue to your satisfaction, you can report it to the [*state*] Equal Employment Opportunity office [*contact info*].

Threats, attempts or actual incidents of physical or sexual assault are all criminal offenses and can be reported to your local police service.

6.2. Assurance of Non-Retaliation

Employees are reminded that Laboratory is committed to providing you a workplace free of sexual harassment and misconduct in accordance with OHS, human rights and other laws and this Policy. Making you feel free to come forward and report incidents or concerns of sexual harassment is an important part of our commitment. Accordingly, we wish to assure you that you won't be fired, demoted, reassigned, disciplined or subject to any other punishment or adverse treatment from Laboratory or its managers, supervisors and other representatives in retaliation for reporting sexual harassment or misconduct in good faith.

6.3. Bad Faith Complaints

To protect the innocent, Laboratory reserves the right to discipline any employee who knowingly and in bad faith files a false complaint or makes misrepresentations of sexual harassment or misconduct up to and including termination. For purposes of this Policy, a complaint is not considered bad faith merely because the evidence does not ultimately support the allegation. Bad faith requires an investigation finding that the employee who accused another person of sexual harassment or misconduct acted maliciously knowing the accusation was false or recklessly without regard to whether the accusation was true.

7. INVESTIGATION

All reports of sexual harassment, misconduct or other alleged violations of this Policy will be taken seriously and responded to immediately. Where it is determined that the report has merit, an internal investigation will be made by staff members not implicated or in any way involved in the complaint following the fair investigation procedures and protocols set out in the Laboratory Disciplinary Policy.

8. DISCIPLINE

Acts of sexual harassment or misconduct will not be tolerated and will be responded to with appropriate disciplinary action, up to and including termination, based on a thorough investigation of the incident and the surrounding circumstances. Such disciplinary action may include immediate termination, even if the person committing the act has committed no prior offenses or engaged in previous acts of sexual harassment or misconduct.

9. CONTRACTORS & SUBCONTRACTORS

To protect employees from risks of sexual harassment or misconduct by third parties they contact at work, Laboratory will ensure that any contractors and subcontractors hired to perform work at its lab sites are notified of and required to ensure their workers comply with the terms of this Policy and are held accountable for any violations they commit.

Genetic Profiling: Study Casts Doubt on Cost-Effectiveness of Leading Breast Cancer Recurrence Assay

Among the many genetic profiling assays entering the commercial market, few have been more successful than Genomic Heath's Oncotype DX, which is now covered by most of the nation's biggest insurers. But while enough to persuade skeptical insurers, evidence of the test's cost-effectiveness was amassed largely under ideal research protocols. How cost effective is the test under real-world, clinical settings?

The Study

That is the question a new research study published in the *Journal of Clinical Oncology* on Jan. 8 sets out to answer. "As with all new technology, it's important to assess real-world implementation to ensure what we're offering patients is useful to them and doesn't add to the societal and patient cost-burden, which is already very high in cancer care," noted the study's lead author, Young Chandler, Dr.P.H., of Georgetown University.

The Assay

Oncotype DX examines the activity of 21 genes in breast tumor tissue to predict whether a patient would benefit from chemotherapy based on a risk cancer recurrence score. The test is intended for use in newly diagnosed patients with early-stage (stage I, II or IIIa), estrogen receptor-positive, HER2-negative breast cancer. A high-risk score indicates that chemotherapy is advisable; a low-risk score indicates that the patient can consider skipping chemotherapy.

The Cost-Effectiveness Premise

The actual cost-effectiveness of Oncotype DX is based on two crucial assumptions:

- The risk-test score is accurate; and
- Patients will actually follow the guidelines in making treatment decisions based on their scores.

The Methodology

In previous studies of the test, these assumptions held up. But those studies were conducted under ideal conditions in which all patients received the test. The new study changes the parameters and focuses on individuals actually tested in real-world practice. The researchers created a model to compare 25-year incremental costs and quality-adjusted life-years (QALYs) based on community use of Oncotype DX from 2005 to 2012. Results were compared to usual care in the pretesting era (2000 to 2004).

The Findings

From 2005 to 2012, the testing rate among eligible patients in community practice was 24% percent and chemotherapy use rate was 30%. In community practice, treatment decisions sometimes ran contrary to test findings. Thus 17% to 26% of patients with high-recurrence risk scores did not receive chemotherapy as the guidelines recommended; meanwhile, 8% of patients opted for chemotherapy anyway despite having low risk scores.

The incremental cost-effectiveness ratio of breast cancer management using Oncotype DX testing as observed in community practice versus usual care without testing was $188,125 per QALY ($100,000 per QALY is the usual benchmark for cost effectiveness). The researchers found that under ideal conditions including perfect test accuracy, the cost-effectiveness ratio was $39,496 per QALY, which is more similar to earlier estimates.

However, cost-effectiveness increased under different scenarios, including lower test costs, higher test accuracy, greater adherence to test-suggested treatment and consideration of the benefits of testing on quality of life.

- If Oncotype DX costs declined from $3,416 (the current Medicare reimbursement rate) to $2,657, the incremental cost-effectiveness ratio of community practice vs. usual care decreased to $71,250 per QALY;
- Adherence to test-concordant treatment lowered the cost-effectiveness ratio to $85,490 per QALY;
- When factoring in the effects of worry or reassurance as a result of information on recurrence risk, the incremental cost-effectiveness ratio for testing was $58,431 per QALY.

Genomic Health's Response

Genomic Health issued a statement to *HemOnc Today* to respond to the study and point out limitations of the study's model including the assumption that Kaiser Permanente patient and testing data was representative of all of community practice. The company added, "Cost-effectiveness analyses are very complex and highly sensitive to the assumptions underlying the economic model. To truly understand the economics of diagnostic testing, it is important to look for consistency across multiple economic studies."

Value Care: CMS Value Modifier Programs Ends Not with a Bang but a Whimper

Thanks for nothing. While CMS likes to congratulate itself for using provider pay adjustments to "transform the healthcare delivery system," more often than not, the rhetoric fails to live up to the reality. Case in point: the Value Modifier, the pay-for-performance program started in 2015 that offers a Medicare reimbursement bump to clinicians, i.e., physicians, nurse practitioners, physician assistants, clinical nurse specialists, and certified registered nurse anesthetists for hitting specific patient care quality metrics. The size of the increase ranges (in 2018, the range was 6.6% to 19.9%) based on an actuarial formula.

The 2018 Adjustments

On Jan. 12, CMS announced the adjustments for 2018, the last year of the program. The results were pretty underwhelming. Thus of the over 1.1 million eligible clinicians:

- Only 20,480, or 1.8%(!), earned the promised positive payment bump;

- Nearly 300,000, or 25.8%, qualified for negative adjustments that in previous years would have earned them a pay cut but won't result in pay cuts in 2018 due to rules changes; and
- The "overwhelming majority," i.e., 744,556, or 64%, qualified for neutral pay adjustments.

Bottom line: In 2018, 98.2% of clinicians will get to Value Modifier adjustments. This year's uninspired results are pretty consistent with the previous two years of the program, as illustrated by the Table below.

Value Modifier Payment Adjustment	2018				2017	2016	2015
	Total Practices		Total Clinicians		Total Physicians		
	#	%	#	%	%	%	%
All upward payment adjustments (1.0x, 2.0x, 3.0x in 2018)	3,478	1.7%	20,481	1.8%	1.4%	0.9%	3.2%
Neutral payment adjustment due to performance	74,024	35.7%	746,556	64.8%	61.3%	65.3%	72.1%
Neutral payment adjustment due to holding harmless from performance	8,007	3.9%	87,841	7.6%	1.3%	3.8%	NA
Downward adjustment due to performance	NA	NA	NA	NA	3.0%	2.2%	1.1%
Downward adjustment due to lack of quality reporting	121,642	58.7%	296,475	25.8%	33.0%	27.8%	23.6%
Total Value Modifier Practices & Clinicians	**207,151**	**100%**	**1,151,353**	**100%**	**100%**	**100%**	**100%**

Takeaway: Perhaps mercifully, 2018 is the final year of the Value Modifier program which is being phased out in favor of the new Merit-based Incentive Payment System (MIPS) and Advanced Alternative Payment Models (APMs). It remains to be seen whether the new models will have more impact than their predecessor.

Influenza Testing: Study Finds Older Patients Are Under-Tested and Under-Diagnosed

The worst flu season in years adds immediacy to a new study tracking flu test utilization patterns based on age. *The key finding:* Older adults hospitalized with fever or respiratory symptoms during flu seasons are less likely than younger patients to have a provider-ordered flu test.

Age as a Factor in Flu Risk

Existing evidence suggests that older adults are disproportionately hospitalized for the flu and that early diagnosis and treatment improves outcomes.

The U.S. Centers for Disease Control and Preventions says that a total of 8,990 laboratory-confirmed influenza-associated hospitalizations were reported between Oct. 1, 2017, and Jan. 13, 2018. During that period:

- The overall hospitalization rate was 31.5 per 100,000 people;
- The highest rate of hospitalization was among adults 65 and over (136.5 per 100,000); and
- The next highest rate was among followed by adults age 50 to 64 (33.2 per 100,000) followed by children age 0 to 4 (22.8 per 100,000).

The Study

Published online in the *Journal of the American Geriatrics Society* on Jan. 17, 2018, the study was performed by researchers from Vanderbilt University led by Lauren Hartman, M.D., who assessed influenza testing among 1,422 adults hospitalized with acute respiratory illness or nonlocalizing fever at four hospitals (one academic and three community facilities) in Tennessee between November 2006 and April 2012. They prospectively performed reverse-transcriptase polymerase chain reaction (RT-PCR) influenza testing for all patients, even if the patients' providers had not ordered it. The researchers then compared demographic and clinical characteristics of patients whose providers had ordered testing with those of patients for whom laboratory-based diagnostic tests had not been ordered.

The Findings

The researchers found that over the study period providers requested tests for just over one-fourth of patients (28%). They also found an age disparity between tested and untested patients. Thus, the average age for tested patients was 58 versus 66 for untested patients. Part of this difference is attributable to the fact that tested patients were more likely to have flu-like symptoms (e.g. fever, cough, and/or sore throat), which decreased with age.

RT-PCR testing identified flu in 10% of patient; but among those patients with confirmed flu, 43% did not have test orders placed by their providers. Patients receiving care in the academic hospital were more likely to have provider-ordered influenza tests (41% versus 20% in community hospitals). The 450 provider-ordered tests were primarily for antigen detection (97.0%), 7.3% were for viral culture and 8.5% were for RT-PCR.

The Challenge Ahead

"The challenge of influenza diagnosis in hospitalized older adults is to not only identify cases clinically, but select an appropriate sensitive diagnostic test such as RT-PCR," write Hartman and her colleagues. "Further strategies are needed to increase clinician understanding of these challenges in clinically identifying influenza in older adults, as well as the limitations of diagnostic tests, to better diagnose and treat cases of influenza in this vulnerable population."

Takeaway: When it comes to flu, older, hospitalized patients are under-tested and under-diagnosed. And even when testing is ordered, it is most often not for sensitive diagnostic tests, like RT-PCR.

FDA Watch: Extra Time for Comments on CLIA IVD Waiver Proposals

Securing CLIA waivers for *in vitro* diagnostic (IVD) medical devices from the FDA is a time-consuming and cumbersome process So, the FDA won rare plaudits from the industry on Nov. 29, 2017, by setting out a pair of draft guidance documents proposing to loosen up the rules. The original deadline for comment was 90 days from publication. But at the end of January, the agency announced that it was pushing the deadline back to March 30. Here's a down and dirty on each proposal.

The Demonstrating Insignificant Risk of Erroneous Result Draft Guidance

The first draft guidance lays out two options sponsors can use to demonstrate accuracy, i.e., "insignificant risk of erroneous result," of *in vitro* diagnostic tests for purposes of obtaining a CLIA waiver:

- Demonstrate accuracy of the test when performed by trained operators as part of the marketing submission via comparison to a traceable calibration (or reference) method and then leveraging the data in combination with a new study to demonstrate agreement between results of the test performed by untrained and trained operator in the waiver by application submission; or
- Where the sponsor chooses to demonstrate the test's substantial equivalence or safety and efficacy when performed by trained operators in the marketing application *without* demonstrating accuracy via comparison to a traceable calibration (or reference) method, "the sponsor [may] demonstrate accuracy of the test when performed by untrained operators through direct comparison to a traceable calibration method (or reference method), or other comparative method performed in a laboratory setting by trained operators in the waiver application."

The Dual Pathway Draft Guidance

The second draft guidance aims to make the dual CLIA waiver and Section 510(k) clearance pathway for certain Class I and Class II IVD devices created in 2012 less burdensome. Among other things, the guidance recommends that manufacturers include as part of a dual submission:

- A device description and determination that the device is "simple";
- A risk analysis for the device;
- A description of its failure-alert and fail-safe mechanisms;
- Results of flex, analytical, comparison and reproducibility studies; and
- Proposed device labelling.

Takeaway: Reading between the lines and based on previous agency activity, extension of the comment periods could be a positive sign presaging quick adoption of both proposals. On the other hand, the delay could just be attributable to the timing of the original comment period during the holiday season and calendar wrap around. So stay tuned.

Case of Month: Using Window Envelope to Mail HIV Info Costs Aetna $17+ Million, *from page 1*

The Fallout

The story takes on a grotesque dimension when you consider the hundreds of millions of dollars firms like Aetna invest each year to secure the personal medical data with which they are entrusted from high-tech hacking and cyber-attack. But to the extent it serves as a reminder of the potential of low-tech breaches to do life-shattering privacy damage, the Aetna debacle might prove a long-term positive.

The Takeaway

First and most obvious, remember that window envelopes and medical information can be a lethal mix. As for post cards, don't even think about it. Finally, labs and other providers would do well to take heed of the privacy measures the settlement agreement imposes on the administrator in charge of executing and notifying the affected Aetna beneficiaries of the settlement:

- The envelope containing the notice must obscure the envelope's contents;
- The return address must be devoid of any identifying information other than a P.O. box, city, state and ZIP Code; and
- There must be a statement on the envelope front stating: "Confidential Legal Information—To Be Opened Only By The Addressee."