PMC PERSONALIZED MEDICINE COALITION

PMC Policy Committee Meeting
Monday, October 16, 2017, 2:30 p.m. ET

Business Meeting: Supplemental Materials

Contents:

1. PMC comment letter to Representatives Bucshon and DeGette on the discussion draft of the "Diagnostic Accuracy and Innovation Act (DAIA)" (submitted July 17, 2017)

2. PMC comment letter on CMS' Outpatient Prospective Payment System Proposed Rule – DOS Provision (submitted September 11, 2017)

3. *STAT News* (August 23, 2017). "'Voluntary' workplace wellness programs dealt setback by U.S. court."

4. PMC's *Legislative Update*

PERSONALIZED MEDICINE COALITION

July 17, 2017

The Honorable Larry Bucshon
1005 Longworth House Office Building
Washington, D.C. 20515

The Honorable Diana DeGette
2111 Rayburn House Office Building
Washington, D.C. 20515

Sent via email: Jeffrey.Lucas@mail.house.gov; Polly.Webster@mail.house.gov

Re: "The Diagnostic Accuracy and Innovation Act"

Dear Representatives Bucshon and DeGette:

On behalf of the Personalized Medicine Coalition (PMC), which represents innovators, scientists, patients, providers, and payers to promote the understanding and adoption of personalized medicine concepts, services, and products for the benefit of patients and the health care system, I am writing to share PMC's comments on the discussion draft of the "Diagnostic Accuracy and Innovation Act" (DAIA).

PMC defines personalized medicine as an emerging field that uses diagnostic tools to identify specific biological markers, often genetic, to help determine which medical treatments and procedures will be best for each patient. By combining this information with an individual's medical history and other clinical information, personalized medicine allows doctors and patients to develop targeted prevention and treatment plans. The goal is to provide the right treatment in the right dose to the right patient at the right time.

Our interest in the discussion draft of the DAIA pertains to how it can support this emerging field. We seek to ensure that the field can move forward in enhancing patient care and improving the quality, safety, accuracy, and effectiveness of treatments, with the acknowledgement that innovation and access should be balanced with patient safety.

Many of PMC's members will present their own responses to this discussion draft and will actively advocate for those positions. To support the work of our member organizations, we therefore note the following disclaimer: nothing in these comments is intended to impact adversely in any way the ability of individual PMC members, alone or in combination, to pursue separate comments. Additionally, PMC does not hold a position on whether laboratory-developed tests (LDTs) should be regulated by the Food and Drug Administration (FDA) or by the Clinical Laboratory Improvement Amendments (CLIA) program at the Centers for Medicare & Medicaid Services (CMS). PMC's comments are focused exclusively on personalized medicine issues and are designed to communicate areas of consensus with regard to LDTs, which may be applicable to in vitro clinical tests (IVCTs) as described in the discussion draft.

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Last year, PMC moderated a series of discussions on potential legislative solutions with representatives from much of the diagnostics community, including but not limited to those with an interest in personalized medicine. Six consensus principles emerged from these conversations, and we review them in the context of the draft legislation below. PMC is committed to working with you and the relevant stakeholders on finding additional areas of consensus.

1. **Protect public health labs.**

   Public health labs should be protected by any regulatory paradigm, which means that sentinel, infectious disease, and public health labs must be able to design, deploy, and use rapidly developed diagnostics to address critical public health needs.

   DAIA clearly indicates that FDA review requirements will not apply to tests intended to be used solely for public health surveillance. We appreciate the inclusion of this language and urge you to retain it in any future versions of the legislation.

2. **Allow flexibility and efficiency when managing modifications.**

   As diagnostic device developers have long argued, the way test modifications are managed by a regulatory system should be flexible and efficient to allow diagnostic tests to evolve with the clinical science that underpins them.

   The draft legislation would give FDA the flexibility to approve IVCTs with associated processes for allowing certain modifications, including specimen type, to take place without additional premarket review, as was proposed in FDA's white paper on LDT regulation. PMC believes this is an important feature of the framework so that improvements can be made without delaying access and increasing regulatory costs.

3. **Mitigate regulatory burdens for government and industry.**

   To reduce burdens on government and industry, regulatory agencies should recognize when certain safeguards are already in place. These mitigation strategies can help regulatory bodies keep pace with the rapidly evolving science of personalized medicine diagnostic testing.

   The draft legislation attempts to clearly delineate between FDA- and CLIA-associated activities. However, the requirements associated with adverse event reporting to both FDA and CLIA contained within the draft may not be clearly delineated between the two agencies and therefore appear duplicative. We encourage you to further explore how the two reporting systems can be harmonized or unified to prevent unnecessary administrative burdens and confusion about what types of information should be reported to whom.

4. **Design a grandfathering provision for tests already on the market along with a risk classification system for novel tests.**

   Tech firm Concert Genetics (previously known as NextGxDx) estimates that there are more than 60,000 personalized medicine diagnostics offered by about 300 labs, with another eight to ten coming to market each business day. To manage such an enormous workload, a regulatory agency must design a grandfathering system that will allow most tests to remain on the market unless there is a compelling reason to remove them.

The draft legislation would grandfather all LDTs, but require that developers of non-reviewed, high-risk tests submit certain data to FDA within five years of the bill's enactment. PMC believes this approach lessens the burdens on FDA and laboratories significantly, while also seeking to protect patients by reviewing information associated with tests that could cause a patient serious or irreversible harm, prolonged disability, or death if there is a clinically significant, inaccurate result that goes undetected when the test is used as intended. In addition, the draft legislation would prevent duplication of state activities for grandfathered tests by exempting tests that have already been reviewed by the New York State Department of Health.

Likewise, it is critical that a consistent and transparent risk classification system be described before enactment of new legislation governing the oversight of IVCTs. PMC suggests that the DAIA mandate that FDA develop and publish examples to illustrate the risk classification system in its proposed rule to implement DAIA subject to public review and comment before the new risk-based regulatory oversight framework goes into effect in a final rule. We believe that appropriate detail is needed. For example, FDA should clearly describe what elements of a diagnostic test contribute to high-, moderate-, or low-risk classification. FDA should also outline a process by which it will adapt risk classification for IVCTs that are related to submissions for further intended uses of approved tests and for modifications that may be made to various types of tests during their life cycles.

5. **Ensure regulatory burdens reflect testing volumes.**

   Regulatory burden must reflect testing volume. For example, diagnostics designed for rare and unmet needs should be given careful and different consideration to ensure that tests are developed for micro-markets.

   PMC appreciates that the draft legislation designs a special pathway for tests that fill unmet needs, and provides carve-outs for custom IVCTs and tests for rare diseases. However, the definition of a test for rare diseases might not be sufficient dependent on testing volumes. PMC urges you to consider exemption language to define and cover rare diseases more clearly. We recommend working with stakeholders to find a reasonable solution to this issue.

6. **Accept valid scientific evidence for regulatory purposes — even if that evidence does not include data from a randomized, controlled trial.**

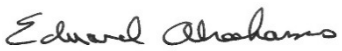
   Personalized medicine challenges how health care products and services are conceived, developed, regulated, covered, paid for, and used by physicians. Evidentiary requirements for regulatory review must also evolve. The community agrees that, regarding diagnostics, valid scientific evidence should be acceptable for regulatory review even when that evidence does not include data from randomized, controlled trials.

   The draft legislation outlines various types of evidence to demonstrate analytical and clinical validity, including peer-reviewed literature, clinical guidelines, case studies or histories, consensus standards, and reference standards. We urge you to retain this language in any future version of the legislation.

PMC appreciates the opportunity to provide comments now and in the future as you work toward the appropriate balance between regulation, innovation, and access to personalized medicine diagnostic tests. We look forward to continue working with you as the process moves forward.

If you have any questions about the content of this letter, please contact me at eabrahams@personalizedmedicinecoalition.org or 202-787-5907.

Sincerely yours,



Edward Abrahams
President

PMC
PERSONALIZED
MEDICINE COALITION

September 11, 2017

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1678-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Sent electronically

Re: CMS-1678-P — Hospital Outpatient Prospective Payment System, Notice of Proposed Rulemaking — Potential Revisions to the Laboratory Date of Service Policy

Dear Administrator Verma:

The Personalized Medicine Coalition (PMC) appreciates the opportunity to submit comments regarding the Centers for Medicare & Medicaid Services (CMS) Hospital Outpatient Prospective Payment System (OPPS) — Notice of Proposed Rulemaking (NPRM): *Medicare Program Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs*.

PMC, which represents innovators, scientists, patients, providers, and payers, promotes the understanding and adoption of personalized medicine concepts, services, and products for the benefit of patients and the health care system. Our interest in the proposed rule pertains to how the concepts therein can support this emerging field. Our comments focus specifically on laboratory date of service (DOS) policy revisions contained in the CMS Hospital OPPS Proposed Rule for Calendar Year (CY) 2018.

Personalized medicine is an emerging field that uses diagnostic tools to identify specific biological markers, often genetic, to help determine which medical treatments and procedures will be best for each patient. By combining this information with an individual's medical history, circumstances, and values, personalized medicine allows doctors and patients to develop targeted prevention and treatment plans in order to provide the right treatment in the right dose to the right patient at the right time.

Personalized medicine is helping to shift the patient and provider experience away from trial-and-error and toward a more streamlined process for making clinical decisions, which will lead to improved patient outcomes, a reduction in unnecessary treatments costs, and better patient and provider satisfaction, particularly for chronic conditions that disproportionately affect Medicare beneficiaries. PMC members are leading the way in personalized medicine and recommend that patients who may benefit from the approach undergo appropriate testing as soon as possible during their clinical experiences.

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Statement of Neutrality

Many of PMC's members will present their own responses to CMS and will actively advocate for those positions. PMC's comments are designed to provide feedback so that the general concept of personalized medicine can advance, and are not intended to impact adversely the ability of individual PMC members, alone or in combination, to pursue separate comments with respect to the proposed rule or related issues. PMC's response is focused exclusively on personalized medicine issues related to the DOS policy revisions outlined in the NPRM.

Acknowledgement of Need for DOS Policy Revision

Personalized medicine depends in part on information from molecular pathology tests, advanced diagnostic laboratory tests (ADLTs), and some multianalyte assays with algorithmic analysis (MAAAs) to inform disease risk, diagnosis, prognosis, and treatment of patients with certain complex conditions.

Under current rules, hospitals are required to bill CMS for molecular pathology tests, ADLTs, and MAAAs that are performed within 14 days after a patient's discharge from the hospital if the tests do not fall under CMS' existing OPPS packaging exceptions, regardless of where the diagnostic tests were conducted. Laboratories outside the hospital must then seek payment directly from the hospital for services performed. In some cases, the administrative burdens caused by this policy led to delayed diagnostic testing that could guide the most appropriate treatment decisions for individual patients. The policy has thereby inadvertently led to a delay in implementing personalized medicine, hindering its adoption in the U.S. health care system.

After publication of the Medicare Physician Fee Schedule final rule in 2006, when it became clear that the laboratory date of service for hospital outpatients is the date a specimen was collected, CMS received public comments highlighting billing complexities, inconsistent coverage, and potential test ordering disincentives that could result from this policy. While the CMS rule did not intend to complicate disease diagnosis, delay treatment, or stifle personalized medicine, PMC applauds CMS' acknowledgement of the problem and its effort to address these concerns in the CY 2018 proposed rule.

Recommendations to Ensure Revised DOS Policy Incentivizes Appropriate Deployment of Personalized Medicine Tests

PMC supports CMS' approach, detailed in the CY 2018 proposed rule, which would allow laboratories to bill Medicare directly for tests that are excluded from the OPPS packaging exemptions. The agency's focus on reducing operational issues caused by the existing policy is laudable. The Coalition urges you, however, to consider the broadest possible application of the proposed changes. To ensure the most rapid and appropriate deployment of personalized medicine, PMC believes specifically that the modifications adopted by CMS in the final rule should not be limited to certain ADLTs but should encompass all ADLTs, molecular pathology tests, and MAAAs, which, as indicated, are integral to personalized medicine. These tests are typically performed outside the hospital using specimens taken from hospital outpatients and have a pattern of clinical use that makes them less connected to the primary services a patient receives in the outpatient setting. We recognize that some specialized hospital laboratories may perform their own molecular pathology tests. In these cases, the hospital would remain the billing entity under a DOS policy revision.

Recommendations to Ensure Revised DOS Policy Can Accommodate Liquid-Based Tests

PMC also encourages CMS to recognize that blood, urine, and other liquid-based tests provide important clinical results and should be considered in revisions to the DOS policy. As written, the CY 2018 proposed rule only allows a performing laboratory to bill for a test if a physician orders the test following the date of a hospital outpatient's discharge, a policy that may be suitable for tissue-based tests where the test is typically ordered after a sample is collected but could result in the exclusion of liquid-based tests, which are generally ordered on or before the date a sample is collected. If a hospital outpatient has not been discharged at the time a test was ordered by the physician and a liquid-based specimen is collected, the hospital is still required to bill Medicare even when a laboratory

performs the service. Removal of the order date requirement from the final rule would level the playing field for liquid-based tests and allow CMS' DOS policy to keep pace with innovation.

Conclusion

In summary, PMC recognizes and appreciates CMS' efforts to address concerns regarding the DOS billing practices set forth in the 2006 Medicare Physician Fee Schedule final rule. The Coalition supports changes to the laboratory DOS policy, and recommends that:

1. Modifications adopted by CMS in the final rule should not only apply to certain ADLTs, but should encompass all ADLTs, molecular pathology tests, and MAAAs.

2. Requirements for test ordering dates after a patient's discharge should be removed to accommodate for differences in specimen collection patterns for liquid-based tests.

Thank you for considering our comments on the laboratory DOS policy changes contained in the CY 2018 proposed rule. PMC and CMS are united by a shared goal of providing access to the safest and most effective medical technologies. If you have any questions about the content of this letter, please contact me at 202-589-1769 or cbens@personalizedmedicinecoalition.org.

Sincerely yours,

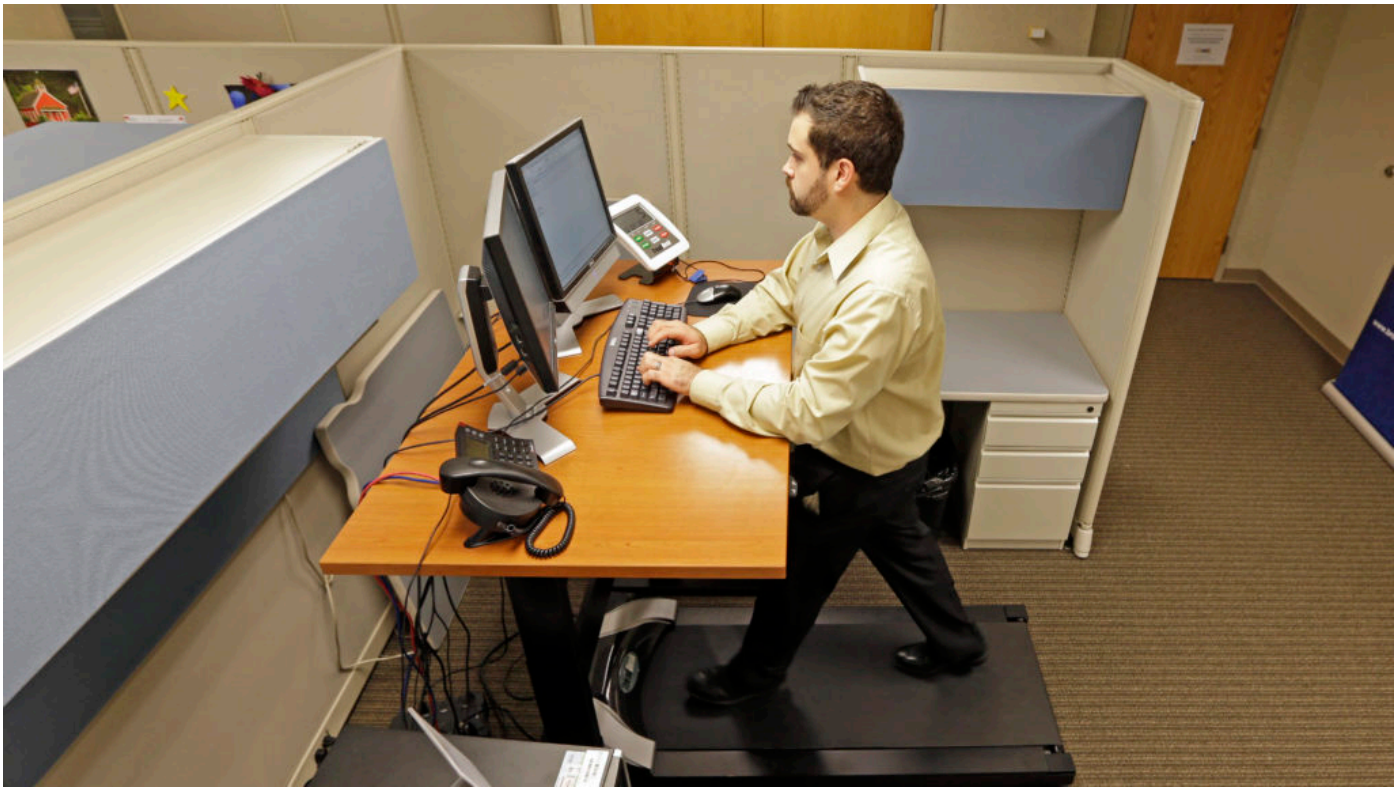
Cynthia A. Bens
Vice President, Public Policy

STAT

‘Voluntary’ workplace wellness programs dealt setback by U.S. court

By Sharon Begley @sxbegle

August 23, 2017



Michael Conroy/AP

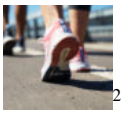
Afederal court on Tuesday threw out a rule allowing employers to call their workplace wellness programs “voluntary” when employees stand to lose thousands of dollars for not participating — a win for groups that challenged what they argue are coercive programs that have not been shown to improve employees’ health[1].

The ruling, a summary judgment for the group that challenged the federal rule, orders the U.S. Equal Employment Opportunity Commission to come up with a “reasoned explanation” for deeming workplace wellness programs voluntary even if the programs impose steep penalties on workers who opt out, calling the absence of such an explanation when the EEOC issued its rule last year “a serious failing.”

The U.S. District Court for the District of Columbia, in an opinion by Judge John Bates, allows the 2016 EEOC rules to stay in place for now, however. Immediately unwinding the penalties and incentives in workplace wellness programs, which are built into employer-based health insurance plans, would be too disruptive, he ruled, since those plans have been in effect for months.

“Employees who received incentives from their employers would presumably be obligated to pay these

back, which may not be feasible for many; employers who imposed a penalty rather than an incentive would likewise be obligated to repay to employees the cost of the penalty, which again, may or may not be feasible,” he said. In addition, “any employees who have chosen to disclose their protected medical information have already done so; this information cannot be made confidential again.”

 [2]

Read More [2]

Top wellness award goes to workplace where many health measures got worse [2]

EEOC Acting Chair Victoria A. Lipnic told STAT that the agency is "assessing the impact of the court's decision and order, and options with respect to these regulations going forward." Deborah Chalfie of AARP, the group that challenged the EEOC, said it "will be difficult" for the agency to come up with a "reasoned explanation" for its view on what makes a workplace wellness program voluntary (or not) "given the judge's decision."

The ruling "is unlikely to be the end of the story and for now nothing changes for employer wellness initiatives," said Steven Wojcik, vice president for public policy at the National Business Group on Health, an association for large employers which supports the wellness programs. "Though the EEOC rules are not perfect, they do clarify underlying ambiguities in the law and have helped assure that employees and their families can benefit from these programs that promote their well-being."

The controversy over the meaning of "voluntary" stems from apparent conflicts among at least three landmark laws. The 1990 Americans with Disabilities Act (ADA) and the 2008 Genetic Information Nondiscrimination Act (GINA) both prohibit employers from asking for or collecting medical or genetic information from employees. But the ADA allows employers to conduct medical examinations and collect employee medical history as part of an "employee health program," as long as participation in the program is "voluntary" — a term the law does not define. GINA has an analogous prohibition on employers asking for, requiring, or purchasing "genetic information" from employees, again with a carve-out for a "voluntary" (again, undefined) wellness program.

Because the EEOC administers both ADA and GINA, it stepped in to define "voluntary" in the context of workplace wellness programs. The programs have become increasingly popular as employers seek ways to reduce their health care spending. In addition, the Affordable Care Act allows employers to offer even higher workplace-wellness incentives than had previously been permitted. Last year, the agency issued a rule saying that "use of a penalty or incentive of up to 30 percent of the cost of self-only coverage will not render 'involuntary' a wellness program that seeks the disclosure" of workers' ADA- and GINA-protected medical or genetic information.

AARP, the membership organization for older Americans, filed its lawsuit challenging that rule last in October. The group argued that when employers are permitted to offer incentives to participate in workplace wellness programs — which often require workers to take blood tests, report their weight and blood pressure and other "biometrics," and disclose other information that landmark laws made private — those programs are not "voluntary," since workers who cannot afford the penalty will be forced to

disclose health and genetic information that they would otherwise choose not to share with their employer.

AARP attorney Dara Smith said the group "is very pleased with this victory for workers' rights. The court's opinion thoroughly dismantled the agency's reasoning, and we expect the agency to have a tough time justifying this rule or a similar one while staying faithful to the purpose of the civil rights statutes."

In issuing a summary judgment against the EEOC, the court noted that the agency had long viewed the use of incentives for workplace wellness participation as making such participation no longer truly voluntary, and took the agency to task for not explaining why, in its 2016 rule, it reversed course. "The

Court can find nothing … that explains the agency's conclusion that the 30 percent incentive level is the appropriate measure for voluntariness," Bates wrote. The penalty for not giving an employer medical information "is the equivalent of several months' worth of food for the average family, two months of child care in most states, and roughly two months' rent," suggesting that such steep penalties make workplace wellness participation less than voluntary.

Business groups that support workplace wellness programs are working with congressional Republicans on legislation[4] that would remove the restraints that the ADA and GINA place on the programs. It is not clear if congressional leaders plan to move the bill, H.R. 1313, forward when they return to Washington next month.

Attorney Barbara Zabawa, president of the Wisconsin-based Center for Health and Wellness Law, said she "was surprised that the Court found the EEOC's administrative rules to be arbitrary and capricious." Recent U.S. Supreme Court cases have deferred to federal agencies' interpretations of what various laws allow. But President Trump's appointee, Neil Gorsuch, "is known to have questioned the validity" of such deference, Zabawa said, raising the possibility that "courts will be more critical of an agency's interpretation."

This story was updated with comments from additional organizations.

About the Author

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PMC PERSONALIZED MEDICINE COALITION

Legislative Update
Personalized Medicine Coalition
115th Congress – 1st Session

Diagnostic Regulation

Discussion Draft: [Diagnostic Accuracy and Innovation Act (DAIA)] (view draft)
Sponsors: Reps. Larry Bucshon (R-IN-8) and Diana DeGette (D-CO-1)
Description: A bill to establish a regulatory framework for in vitro clinical tests that advances innovation for patient benefit, protects patients, provides a predictable and timely path to market, ensures reasonable risk-based regulation, avoids duplicative regulation, advances precision medicine, and applies the same regulatory principles to the same activity regardless of entity type, and for other purposes.
Summary: "In vitro clinical tests (IVCTs) would have their own regulatory structure under the Food, Drug, and Cosmetic Act—separate and apart from traditional medical devices—that was developed with their unique attributes in mind from the outset. To eliminate duplicative regulation, the [DAIA] clearly establishes FDA jurisdiction over test development and manufacturing activities and maintains oversight of laboratory operations under the Centers for Medicare and Medicaid Services (CMS) pursuant to an updated Clinical Laboratory Improvement Amendments (CLIA) framework" (from Buschon's press release).
Status: March 20, 2017 – Discussion draft released by Representatives Bucshon and DeGette

Use of Genetic Information

H.R. 1313: Preserving Employee Wellness Programs Act (view bill)
Sponsor: Rep. Virginia Foxx (R-NC-5); Co-Sponsors: 0 Democrats, 5 Republicans
Description: A bill to clarify rules relating to nondiscriminatory workplace wellness programs.
Summary: This bill exempts workplace wellness programs from: (1) limitations under the Americans with Disabilities Act of 1990 on medical examinations and inquiries of employees, (2) the prohibition on collecting genetic information in connection with issuing health insurance, and (3) limitations under the Genetic Information Nondiscrimination Act of 2008 on collecting the genetic information of employees or family members of employees. This exemption applies to workplace wellness programs that comply with limits on rewards for employees participating in the program.
Workplace wellness programs may provide for more favorable treatment of individuals with adverse health factors, such as a disability.
Collection of information about a disease or disorder of a family member as part of a workplace wellness program is not an unlawful acquisition of genetic information about another family member.
Status: March 8, 2017 – Ordered to be reported (amended) by the Yeas and Nays: 22 – 17 by the House Education and the Workforce Committee.

Research on the Use of Genetic Testing

Discussion Draft: Advancing Access to Precision Medicine Act (view draft)
Sponsor: Rep. Swalwell (D-CA-15)
Description: A bill to provide for a study by the National Academy of Medicine on the use of genetic testing to improve health care, and for other purposes.

(continued on back)

Reimbursement & Coverage

S. 794: Local Coverage Determination Clarification Act of 2017 (view bill)
Sponsor: Sen. Johnny Isakson (R-GA); Co-Sponsors: 4 Democrats, 6 Republican
Summary: This bill amends title XVIII (Medicare) of the Social Security Act to revise the process by which Medicare administrative contractors (MACs) issue and reconsider local coverage determinations (LCDs) that: (1) are new, (2) restrict or substantively revise existing LCDs, or (3) are otherwise specified in regulation. (MACs are private insurers that process Medicare claims within specified geographic areas.) …. (view summary)
Status: March 30, 2017 – Introduced in Senate and referred to the Committee on Finance.

Funding for Biomedical Research and FDA

H.R. 3358: Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2018 (view bill)
Sponsor: Rep. Tom Cole (R-OK-4)
Excerpt: For carrying out the responsibilities of the Office of the Director, NIH, $1,705,248,000…. For necessary expenses to carry out the purposes described in section 1001(b)(4) of the 21st Century Cures Act, in addition to amounts available for such purposes in the appropriations provided to the NIH in this Act, $496,000,000, to remain available until expended….
Status: July 24, 2017 (House) – Placed on the Union Calendar, Calendar No. 176.

S. 1771: Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2018 (view bill)
Sponsor: Sen. Roy Blunt (R-MO)
Excerpt: For carrying out the responsibilities of the Office of the Director, NIH, $1,796,970,000…. For necessary expenses to carry out the purposes described in section 1001(b)(4) of the 21st Century Cures Act, in addition to amounts available for such purposes in the appropriations provided to the National Institutes of Health in this Act, $496,000,000, to remain available until expended….
Status: September 7, 2017 – Placed on Senate Legislative Calendar under General Orders Calendar No. 215.

S. 1603: Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2018 (view bill)
Sponsor: Sen. John Hoeven (R-ND)
Excerpt: For necessary expenses of the Food and Drug Administration … $5,146,945,000…. For necessary expenses to carry out the purposes described under section 1002(b)(4) of the 21st Century Cures Act, in addition to amounts available for such purposes under the heading "Salaries and Expenses", $60,000,000, to remain available until expended….
Status: July 20, 2017 – Placed on Senate Legislative Calendar under General Orders. Calendar No. 177.

H.R. 3268: Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2018 (view bill)
Sponsor: Rep. Robert Aderholt (R-AL-4)
Excerpt: For necessary expenses of the Food and Drug Administration … $5,145,945,000…. For necessary expenses to carry out the activities described in section 1002(b)(4) of the 21st Century Cures Act (Public Law 114–255), in addition to amounts available for such activities under the heading "Salaries and Expenses", $60,000,000, to remain available until expended, is provided for Department of Health and Human Services—Food and Drug Administration—FDA Innovation Account.
Status: July 17, 2017 – Placed on the Union Calendar, Calendar No. 165.

H.Con.Res. 71: Establishing the congressional budget for the United States Government for fiscal year 2018 and setting forth the appropriate budgetary levels for fiscal years 2019 through 2027 (view bill)
Sponsor: Rep. Diane Black (R-TN-6)
Status: Motion to reconsider laid on the table Agreed to without objection. 10/05/2017

S.Con.Res. __: Setting forth the congressional budget for the United States Government for fiscal year 2018 and setting forth the appropriate budgetary levels for fiscal years 2019 through 2027 (view draft)
Status: [just went through markup]