



Health Policy Briefing

June 5, 2017

Energy and Commerce Considers Off-Label Communication Ahead of FDARA Markup

Members and staff of the House Energy and Commerce Committee are debating a proposal to expand the ability of drug and device manufacturers to engage in off-label communication as a part Food and Drug Administration Reauthorization Act (FDARA) negotiations. The Medical Product Communications Act (H.R.1703), sponsored by Rep. Morgan Griffith (R-Va.), would allow communication about unapproved uses of products if the information is supported by scientifically appropriate and statistically sound data, and includes a statement noting that the FDA has not approved the drug or device for the discussed use. Democrats are opposed to the bill's inclusion in legislation to reauthorize the FDA's user fee programs, asserting that they already compromised on the issue of off-label communications in the 21st Century Cures Act. The Energy and Commerce Committee had originally signaled that it would hold a full-Committee markup of FDARA before adjourning for Memorial Day recess, but delayed scheduling the markup because of this disagreement. The Senate's user fee package, which has already been advanced out of committee, does not address off-label communications.

Lawmakers Urge More Flexibility for Third-Party Payment Policy

Reps. Kevin Cramer (R-N.D.) and Doris Matsui (D-Calif.) have written to Secretary of the U.S. Department of Health and Human Services (HHS) Tom Price outlining their concerns with policies regulating charitable assistance for health insurance premiums. Restrictions currently exist on third-party payments intended to subsidize premiums for patients in qualified health plans, which the lawmakers believe have the negative effect of steering patients toward government programs. "We urge HHS to...issue a new rule that adds the following to the existing list of entities from which premium and cost sharing assistance is required to be accepted: (1) nonprofit charitable organizations; (2) places of worship; and (3) local civic organizations," the letter states. An additional 182 members of the House of Representatives signed on to the letter.

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Soon Shiong Named to HIT Advisory Committee

Speaker of the House Paul Ryan (R-Wis.) has appointed Patrick Soon Shiong, MD, a controversial billionaire entrepreneur, to serve on the Health IT Advisory Committee which replaces the Health IT Policy Committee per last year's 21st Century Cures Act. The Committee provides recommendations to the National Coordinator for Health Information Technology on policies, standards, implementation specifications, and certification criteria relating to the implementation of a health information technology infrastructure that advances the electronic access, exchange, and use of health information. The Secretary of Health and Human Services and Congressional leadership appoints eleven of the 25 members. The remaining 14 appointments are made by the Government Accountability Office (GAO) and are expected in July. Other recently announced congressional appointees include Steve Ready, CIO of Norton Healthcare (appointed by Senate Majority Leader McConnell); and Steven Lane, an informaticist at Sutter Health in the Bay Area (appointed by House Minority Leader Nancy Pelosi). The law provides that the members of the Health IT Advisory Committee include providers, ancillary health care workers, consumers, purchasers, health plans, health information technology developers, researchers, patients, relevant Federal agencies, and individuals with technical expertise on health care quality, system functions, privacy, security, and on the electronic exchange and use of health information, including the use standards for such activity.

Trump Administration Staff Announcements

The White House announced several additions to senior leadership at the Centers for Medicare and Medicaid Services (CMS) last week. **Brady Brookes** will serve as deputy chief of staff for the CMS office of the administrator. Brooks worked as Vice President Mike Pence's legislative director during his time as governor of Indiana. **Carla DiBlasio**, former advisor to Tom Price during his time in Congress, was named a senior advisor for Medicare. **Calder Lynch** was appointed senior counselor to the administrator for Medicaid. He has previously worked as a health official in Nebraska and Louisiana. **Claire Burghoff**, former aide to Rep. Steve Womack (R-Ark.), will work as a special assistant to the CMS administrator. **Jeet Guram** was named a senior advisor for the CMS Innovation Center and Medicaid. He has previous experience at the Heritage Foundation. **Brenda Destro** is a Special Assistant at the U.S. Department of Health & Human Services. Destro previously served as a senior health policy advisor for Senator Bill Cassidy, MD and for the House Energy and Commerce Committee.

This Week on the Hill

U.S. Department of Health and Human Services (HHS) Secretary Tom Price is scheduled to testify before the House Ways and Means Committee and the Senate Finance Committee on June 8. He will field questions about the Administration's fiscal year (FY) 2018 budget proposal, which includes significant cuts to biomedical research and the Medicaid program. The Senate Finance Committee will also consider the nomination of Eric Hargan to be Deputy Secretary of Health and Human Services on June 7. Hargan has previously worked as HHS deputy general counsel, principal associate deputy secretary, and acting deputy secretary during the George W. Bush Administration.

OIG Estimates EpiPen Overpayments

The U.S. Department of Health and Human Services (HHS) Office of the Inspector General (OIG) estimates that the Medicaid program could have overpaid as much as \$1.27 billion for EpiPen because the product was misclassified as a generic rather than a brand name drug. The OIG examined program spending between 2006 and 2016. The estimate was in response to an inquiry from Sen. Chuck Grassley (R-Iowa). The OIG's findings greatly exceed the \$465 million in overpayments that was previously reported by Mylan, the manufacturer of EpiPen. The company has not responded to requests for information from Sen. Grassley about why the product was misclassified, and why Mylan failed to correct the situation when it was brought to their attention.

Senate Considers Employee Health Plan Tax

The Wall Street Journal has reported that Republicans are considering including a tax on employer health plans as a part of the Senate GOP's health care legislation. The tax would generate billions of dollars in revenue and could help create incentives to reign in health care spending growth. The idea was considered by Speaker of the House Paul Ryan (R-Wis.), but ultimately not included in the House-passed American Health Care Act (AHCA).

GAO: CMS Should Track MA Dropouts

The Government Accountability Office (GAO) has recommended that the Centers for Medicare and Medicaid Services (CMS) should track whether the Medicare Advantage enrollees who drop out of managed care plans are getting adequate care. The GAO report found that beneficiaries in poorer health are more likely than others enrolled in Medicare Advantage to voluntarily leave their health plans. These plans tended to have lower quality scores, with enrollees more likely to face difficulty in accessing care. The plans were also more likely to be restricted provider network health maintenance organizations. The GAO suggests that CMS take advantage of the opportunity to use disenrollment data to better target oversight and identify problems within the Medicare Advantage program. The GAO study was requested by Sen. Sherrod Brown (D-Ohio) and Rep. Rosa DeLauro (D-Conn.) in 2015.

Lawmakers Request 340B Audit Information

Energy and Commerce Committee Chairman Greg Walden (R-Ore.), Oversight and Investigations Subcommittee Chairman Tim Murphy (R-Pa.) and Health Subcommittee Chairman Michael Burgess (R-Texas) have **written** to the Health Resources and Services Administration (HRSA) requesting the last two years of audit documents for the 340B drug pricing program. "The Committee is concerned about the 340B program's rapid growth without additional and proportional oversight," the lawmakers write. They outline a number of concerns with the drug pricing program, including entities billing for duplicate discounts on the same medication, and uninsured or underinsured patients paying the full list price despite the 340B hospital receiving the discounted price. They also note that HRSA doesn't always follow up on audits when program violations are found. The lawmakers express support for the tracking of 340B program savings, and how the savings are spent by covered entities. The lawmakers request that the audit documentation be provided no later than June 15.

NAS To Address HIPAA Laboratory Results Discrepancy

The National Academies of Science (NAS) announced plans to address a discrepancy that exists between HIPAA privacy rules and laboratory testing results. While HIPAA requires research subjects to have access to their data upon request, this data can only be shared if it comes from a research laboratory certified under the Clinical Laboratory Improvement Amendments (CLIA). Most research laboratories in academic medical centers aren't CLIA certified. A NAS committee will make recommendations on how to return individual research results under the current regulatory framework. The project comes as the National Institutes of Health (NIH) works to recruit one million people for the Precision Medicine Initiative.

Upcoming Congressional Hearings and Meetings

Senate Finance Committee Nominations Hearing; 10:00 a.m., 215 Dirksen Bldg.; June 7

House Veterans' Affairs Committee Hearing "Overcoming PTSD: Assessing VA's Efforts to Promote Wellness and Healing;" 10:00 a.m., 334 Cannon Bldg.; June 7

House Ways and Means Committee Medicare Advantage Hearing on Promoting Integrated and Coordinated Care for Medicare Beneficiaries; 2:00 p.m., 1100 Longworth Bldg.; June 7

Senate Finance Committee Hearing on Administration's HHS FY 2018 Budget Request; 10:00 a.m., 215 Dirksen Bldg.; June 8

House Veterans' Affairs Oversight and Investigations Subcommittee Hearing "VA and Academic Affiliates: Who's Benefiting Now?;" 10:00 a.m., 334 Cannon Bldg.; June 8

House Ways and Means Committee Hearing on the Department of Health and Human Services' Fiscal Year 2018 Budget Request; 1:00 p.m., 1100 Longworth Bldg.; June 8

House Energy and Commerce Oversight and Investigations Subcommittee hearing "Examining the Role of the Department of Health and Human Services in Health Care Cybersecurity;" 10:15 a.m., 2322 Rayburn Bldg.; June 8

House Energy and Commerce Health Subcommittee Hearing "Examining H.R. 772, The Common Sense Nutrition Disclosure Act of 2017;" 9:00 a.m., 2123 Rayburn Bldg.; June 9