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ONE HUNDRED THIRTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
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MEMORANDUM

July 28, 2014

To: Energy and Commerce Committee Democratic Members and Staff

Fr: Committee on Energy and Commerce Democratic Staff

Re: Full Committee Markup of H.R. 3670, "Anti-Spoofing Act of 2013;" H.R. 5161, "E-LABEL Act;" H.R. 1575, "Kelsey Smith Act;" H.R. 4701, "Lyme and Tick-borne Diseases Act;" H.R. 3522, "Employee Health Care Protection Act;" H.R. 4067, a bill to provide for the extension of the enforcement instruction on supervision requirements for outpatient therapeutic services in critical access and small rural hospitals through 2014; and, H.R. ___, a bill to require the Secretary of Health and Human Services to provide for recommendations for the development and use of clinical data registries for the improvement of patient care.

On Tuesday, July 29, 2014, at 4:00 p.m. in room 2123 of the Rayburn House Office Building, the full Committee on Energy and Commerce will conduct opening statements for the markup H.R. 3670, "Anti-Spoofing Act of 2013;" H.R. 5161, "E-LABEL Act;" H.R. 1575, "Kelsey Smith Act;" H.R. 4701, "Lyme and Tick-borne Diseases Act;" H.R. 3522, "Employee Health Care Protection Act;" H.R. 4067, a bill to provide for the extension of the enforcement instruction on supervision requirements for outpatient therapeutic services in critical access and small rural hospitals through 2014; and, H.R. ___, a bill to require the Secretary of Health and Human Services to provide for recommendations for the development and use of clinical data registries for the improvement of patient care. The Committee will reconvene on Wednesday, July 30, at 10:00 a.m. in 2123 Rayburn House Office Building.

I. H.R. 3670, ANTI-SPOOFING ACT OF 2013

Caller ID is a service used by many Americans to identify telephone callers. Using a practice known as "caller ID spoofing," callers can deliberately falsify the telephone number and name relayed as the Caller ID information to disguise the identity of the calling party.[1] By

[1] Federal Communications Commission, *Caller ID and Spoofing* (online at fcc.gov/guides/caller-id-and-spoofing) (accessed July 21, 2014).

making it appear that a call is originating from a person's bank, credit card company, police station, or other trusted source, identity thieves can extract sensitive personal information that can be used to cause financial harm.

In December 2010, President Obama signed into law the Truth in Caller ID Act, which gave the Federal Communications Commission (FCC) the authority to prohibit any person or entity from transmitting misleading or inaccurate caller ID information with the intent to defraud, cause harm, or wrongfully obtain anything of value.[2] In June 2011, pursuant to a requirement in the Truth in Caller ID Act, the FCC issued a report to Congress with recommendations on how to improve the law, which included broadening the scope of the law to include a prohibition on caller ID spoofing directed at people in the United States by persons outside the United States and providing further guidance on interconnected Voice over Internet Protocol (VoIP) services. The report also recommended adding text messaging to the list of services covered by the law and requiring legitimate third-party spoofing providers to take steps to verify that their users, such as law enforcement or a women's shelter, are informed of applicable Federal or State laws.[3]

On December 6, 2013, Reps. Meng, Barton, and Lance introduced H.R. 3670, the Anti-Spoofing Act of 2013, which incorporated several of the FCC's 2011 recommendations. On July 21, 2014, the majority released new draft language of H.R. 3670, in the form of an amendment in the nature of a substitute from Mr. Barton. Specifically, the substitute amendment would prohibit spoofing by callers outside the U.S. and expand the scope of existing anti-spoofing law to cover new forms of VoIP, as well as text messaging services.

II. H.R. 5161, E-LABEL ACT

On July 10, 2014, Senators Fischer and Rockefeller introduced S. 2583, the E-LABEL Act, that requires the FCC to adopt new rules or "take other appropriate action, as necessary" to allow certain devices with display screens to digitally display required labeling and regulatory information in lieu of physical labels. A House companion bill, H.R. 5161, is sponsored by Reps. Latta, Eshoo, Blackburn, and Welch. On July 11, 2014, the FCC issued guidance on how devices with an integrated display screen, which are currently subject to Commission certification or conformity requirements, can present the required label and regulatory information electronically in lieu of a physical label or nameplate.[4]

III. H.R. 1575, KELSEY SMITH ACT

On April 15, 2013, Reps. Yoder, Pompeo, Jenkins, and Cleaver introduced H.R. 1575, the Kelsey Smith Act, which requires certain communications providers to share call location

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[2] *Id.*

[3] Federal Communications Commission, *Caller Identification Information in Successor or Replacement Technologies* (June 22, 2011) (online at apps.fcc.gov/edocs_public/attachmatch/DA-11-1089A1.pdf).

[4] Federal Communications Commission, *Electronic Labeling Guidance* (July 11, 2014) (online at apps.fcc.gov/kdb/GetAttachment.html?id=KvMvDHtHyDtJ4FB3x0mEwA%3D%3D).

information with a law enforcement official when the information is necessary to respond to an emergency call, or in an emergency situation that involves risk of death or serious physical harm. The bill also provides liability protection for communications providers that act in good faith and in accordance with the terms of the bill.

IV. H.R. 4701, LIME AND TICK-BORNE DISEASES ACT

There are a number of federal activities related to Lyme disease and other tick-borne diseases. The National Institute of Allergy and Infectious Diseases (NIAID) has a Lyme disease research program that focuses on improving the diagnosis, treatment, and prevention of Lyme disease.[5] The Centers for Disease Control and Prevention (CDC) collects data on the number of Lyme disease cases reported to state health departments, conducts epidemiological investigations, offers diagnostic and reference laboratory services, develops and tests prevention and control strategies, and supports education activities for the public and health care providers related to Lyme disease.[6]

NIAID, CDC, and the Food and Drug Administration (FDA) are also part of the HHS Lyme and Tick Borne Diseases Work Group, which facilitates the coordination and communication of activities related to Lyme disease and other tick-borne diseases.[7] Additionally, the Federal Tick-Borne Disease Integrated Pest Management Workgroup – which includes representatives from CDC, the National Institutes of Health, the Environmental Protection Agency, the Department of Agriculture, the Department of the Interior and the National Science Foundation – shares plans for controlling ticks and pathogens they transmit, collects best practices regarding the management of ticks and tick-borne diseases, and identifies and prioritizes research needs.[8]

H.R. 4701, the Vector-Borne Disease Research and Accountability and Transparency Act of 2014, is sponsored by Congressman Gibson (R-NY). The Subcommittee on Health held a markup of an Amendment in the Nature of a Substitute to H.R. 4701 on June 19, 2014, and approved the legislation for full Committee consideration by voice vote.

As amended on June 19, 2014, H.R. 4701 codified the current HHS Lyme and Tick Borne Diseases Work Group as a permanent working group. This working group would be required to consult with certain stakeholders, hold public meetings, and prepare and update a progress report for Congress including information on the activities of the working group, scientific advances, research questions, progress made in improving outcomes, surveillance

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[5] National Institute of Allergy and Infectious Diseases, *Lyme Disease – Research Overview* (online at www.niaid.nih.gov/topics/lymeDisease/research/Pages/research.aspx).

[6] Centers for Disease Control and Prevention, *Lyme Disease Frequently Asked Questions (FAQ)* (online at www.cdc.gov/lyme/faq/index.html#whattodo).

[7] National Institutes of Health, *Collaboration Details - HHS Lyme and Tick Borne Diseases Work Group,* (online at report.nih.gov/crs/View.aspx?Id=1685).

[8] Environmental Protection Agency, *2013 Tick-Borne Disease IPM Conference* (online at www.epa.gov/pesp/events/2013_tick_meeting.html).

activities, engagement with the public, recommendations for appropriate actions to advance research questions and improve surveillance, and a strategic plan to implement those recommendations.

The Amendment in the Nature of a Substitute that is currently scheduled to be marked up by the full Committee would instead create a new Interagency Lyme and Tick-Borne Disease Working Group. The working group would include seven federal and seven non-federal public members representing a diversity of scientific perspectives. The Secretary of Department of Health and Human Services (HHS) would appoint all of the federal members and five of the non-federal public members, while the Speaker of the House of Representatives and the Majority Leader of the Senate would each appoint one of the non-federal public members. Congressional appointments to a standing committee that will be advising the Department on interagency coordination and research priorities does not seem necessary.

The working group would develop a summary of research and advances related to Lyme disease and other tick-borne diseases, monitor and make recommendations to the Secretary regarding federal activities on Lyme disease and other tick-borne diseases, and hold annual public meetings. The group would submit a report to Congress on its activities every two years, make the report available on the HHS website, and be required to allow any member of the working group to include minority views in this report. Some of the language regarding the responsibilities and reporting of the working group could potentially lead to recommendations that lack the strong, scientific evidence base that should inform public health policy.

The Amendment in the Nature of a Substitute also would require the Secretary of HHS to develop a strategic plan, informed by the summary of research developed by the working group. The strategic plan would include proposed budgetary requirements; a plan for improving diagnosis, treatment, and prevention; a plan for improving outcomes, including outcomes related to chronic and persistent symptoms and infections and co-infections; and a plan to disseminate information developed by the working group to the public, public health departments, and other relevant medical groups.

V. H.R. 5322, EMPLOYEE HEALTH CARE PROTECTION ACT

H.R. 3522 would permit any health insurance issuer offering coverage in the group market in 2013 to continue to offer that coverage in 2014 and beyond. These insurance policies would not have to comply with the Affordable Care Act (ACA) consumer protections that went into effect in 2014.

The legislation would allow insurance companies to discriminate against small businesses if they have an older workforce, more women in their workforce, or if any of their employees or their children have pre-existing health conditions. Under the legislation, these small businesses would face higher premiums and would continue to see their premiums spike year to year if an

employee had an accident, developed a chronic health condition, or had a complicated pregnancy.[9]

Under the legislation, group health insurance plans could continue to impose annual limits on coverage, meaning that insurers could cease to provide any coverage after an individual's care reached a certain overall cost. These plans could also continue to impose extensive waiting periods before individuals could enroll in coverage and they could discriminate against workers with lower compensation by offering them lesser health coverage than highly compensated workers.

Many of the ACA's key reforms impacting the group market had already gone into effect for plans sold in 2013. Since 2011, all insurers are required to spend over 80 percent of premiums on patient care rather than excessive profits and administrative costs. Insurers in the large group market are required to spend at least 85 percent of premiums on patient care. All told, these reforms saved consumers more than $4 billion in 2013 and have resulted in nearly $2 billion in rebates directly to consumers.[10]

Even as these key reforms went into effect, health care cost growth was at record lows and the US added 10 million private sector jobs. The non-partisan Congressional Budget Office (CBO) and the Centers for Medicare and Medicaid Services' (CMS) Actuary have both found that in recent years Medicare and private health care spending have grown at some of the slowest levels in decades.[11]

In March 2014, the Administration announced a transition policy that would allow small groups who purchased coverage in 2013 to remain in that same coverage into 2016.[12] That coverage would not have to comply with ACA consumer protections going into effect in 2014 but it could not be sold to groups purchasing coverage for the first time or switching coverage.

Critics have also charged that the ACA will lead some employers to terminate employer health insurance coverage because the law's new beneficiary protections will be too costly for

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[9] White House, *The Affordable Care Act Helps Small Businesses* (online at www.whitehouse.gov/sites/default/files/docs/the_aca_helps_small_businesses.pdf).

[10] Department of Health and Human Services, Centers for Medicare and Medicaid Services, *80/20 Rule Delivers More Value to Consumers in 2013;* Department of Health and Human Services, *Rebates by State and Market* (July 2014) (online at www.cms.gov/cciio/Resources/Forms-Reports-and-Other-Resources/index.html#Medical Loss Ratio).

[11] Executive Office of the President of the United States, *Trends in Health Care Cost Growth and the Role of the Affordable Care Act* (Nov. 2013) (online at www.whitehouse.gov/sites/default/files/docs/healthcostreport_final_noembargo_v2.pdf).

[12] Center for Medicare & Medicaid Services, *Insurance Standards Bulletin Series—Extension of Transitional Policy through October 1, 2016* (Mar. 5, 2014) (online at www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/transition-to-compliant-policies-03-06-2015.pdf).

businesses. However, according to the latest estimates from CBO, while a small percentage of Americans are expected to transfer out of employer sponsored coverage as a result of the ACA, the overall number of Americans receiving employer-based coverage is expected to grow from 156 million in 2014 to 166 million in 2023, and the number of uninsured is expected to fall by 26 million people.[13] Since Massachusetts enacted health care reforms that were almost identical to those in the ACA, the percentage of employers offering coverage has increased from 72 percent in 2007 to 77 percent in 2010.[14]

VI. H.R. 4067, A BILL TO PROVIDE FOR THE EXTENSION OF THE ENFORCEMENT INSTRUCTION ON SUPERVISION REQUIREMENTS FOR OUTPATIENT THERAPEUTIC SERVICES IN CRITICAL ACCESS AND SMALL RURAL HOSPITALS THROUGH 2014

In the 2009 outpatient prospective payment system (OPPS) final rule, CMS clarified existing policy for physician supervision of outpatient therapeutic services as a condition of payment which has been in place since 2001. CMS policy requires direct supervision by an appropriate physician or non-physician practitioner in the provision of all therapeutic services to hospital outpatients, including Critical Access Hospitals (CAH). These services include clinic services, emergency room services, and observation services. All of these services are provided incident to a physician's service so this implies a physician or non-physician practitioner should be around, as such "incident to" services by definition must be performed by or under the supervision of such personnel.

Depending on the service, Medicare either requires "personal," "direct," or "general" supervision for therapeutic services. "Direct supervision" is the requirement unless otherwise noted. "General supervision" means the service or procedure is furnished under the physician's overall direction and control, but the physician's presence is not required during the performance of the procedure. "Personal supervision" means the physician must be in attendance in the room during the performance of the service or procedure. "Direct supervision" means the physician or other practitioner has to be immediately available—generally at the site where the services are occurring but not personally in the room while the service is being provided. "Direct supervision" requirement does not mean a supervising professional must be within the four walls of the facility, but only that the professional must be "immediately available to furnish assistance and direction throughout the performance of the procedure." Immediate availability requires the immediate physical presence of the supervisory provider. "Direct supervision" may be furnished from a providers' office or other nonhospital space that is not officially part of the hospital or CAH campus where the service is being furnished as long as the supervising provider is immediately available.

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[13] Congressional Budget Office, *April 2014 Estimate of the Effects of the Affordable Care Act on Health Insurance Coverage* (online at www.cbo.gov/sites/default/files/cbofiles/attachments/45231-ACA_Estimates.pdf)

[14] Massachusetts Division of Health Care Finance and Policy, *Health Care in Massachusetts: Key Indicators* (July 2011) (online at www.mass.gov/chia/docs/r/pubs/11/2011-key-indicators-february.pdf).

As a result of concerns raised by CAHs and small rural hospital providers, CMS delayed the enforcement of the supervision requirements in a non-enforcement instruction on March 15, 2010, for critical access hospitals and small rural providers. This non-enforcement instruction was in place from that time through 2013. During that period of non-enforcement, CMS made adjustments to the definition of direct supervision, established an advisory panel (the Hospital Outpatient Payment Panel) to obtain advice on the appropriate supervision levels for individual hospital outpatient therapeutic services, and expanded the list of outpatient therapeutic services for which direct supervision is not required. CMS made these changes in response to concerns and requests made by CAHs and other stakeholders. As of January 1, 2014, however, the non-enforcement instruction has not been in effect, and providers are expected to comply with the supervision rules.

The legislation, H.R. 4067, would mandate that the Secretary of HHS apply the enforcement instruction dated November 1, 2012, for the remainder of Calendar Year 2014 (i.e., the next five months). This would halt the enforcement of these supervision requirements that have been in effect for the past seven months.

Non-enforcement of supervision requirements can have patient safety implications. For example, this would mean that hospital outpatient departments giving toxic doses of chemotherapy medicine would not have to ensure there is a supervising professional in the facility when the patient was being treated.

The Medicare Payment Advisory Commission (MedPAC) had the following to say about the enforcement of these requirements in their 2013 Hospital Outpatient Comment Letter, "In light of the decision to enforce the supervision instructions, we advocate that CMS continue working with the Hospital Outpatient Payment Panel to define services that are appropriate for general supervision. Similarly, we encourage CMS to review Conditions of Participation (CoPs) for CAHs to ensure that the CoPs are consistent with regulations."

VII. H.R. ___, A BILL TO REQUIRE THE SECRETARY OF HEALTH AND HUMAN SERVICES TO PROVIDE FOR RECOMMENDATIONS FOR THE DEVELOPMENT AND USE OF CLINICAL DATA REGISTRIES FOR THE IMPROVEMENT OF PATIENT CARE

Clinical data registries are used for many different purposes, quality improvement, tracking patient outcomes, etc. Some provider organizations have developed registries to collect data for the development of clinical practice guidelines. The Society of Thoracic Surgeons (STS), for example, established a registry in 1989 as an initiative for quality improvement and patient safety among cardiothoracic surgeons. There are drug and device registries that collect information on outcomes and adverse events related to specific products. Some organizations maintain patient registries that provide an organized system to collect data for scientific assessment of patient outcomes.

Both the public sector and the private sector have taken action to develop registries, and also have collaborated, to develop guidelines, best practices, and technical assistance for the development and operation of registries. The Agency for Health Research and Quality (AHRQ)

has issued extensive guidance on how to create registries, for example *Registries for Evaluating Patient Outcomes: A Users Guide*. This extensive document was recently updated with assistance and support from a range of stakeholders, including government agencies, industry groups, medical professional societies, and other experts in the field. AHRQ also maintains a registry of patient registries (RoPR) where the public can search to identify registries on various topic of interest and to prevent duplication in the development of registries.

The American Medical Association (AMA) operates the National Quality Registry Network (NQRN®) which is a voluntary network of organizations operating registries and others interested in increasing the usefulness of clinical registries to measure and improve patient health outcomes. The NQRN Council is composed of members, plus federal government liaisons, who represent registry stewards and participants, non-delivery system registry users, and supporting technologies.

To date, the largest impediment to registry development by medical providers has not been lack of knowledge or guidance, but funding for the creation and maintenance of the registry. The bipartisan bicameral sustainable growth rate (SGR) repeal bill (H.R. 4015) would have given registries access to CMS claims data so the registries could pair the claims data with the clinical data and track both outcomes and efficiencies.

The Committee Print, H.R. ___, would direct the Secretary of HHS to make recommendations for the development and use of clinical data registries that are integrated with clinical practice guidelines and best practices or standards of care. The legislation provides five paragraphs of extensive instruction for what these recommendations should cover. Because of the varied nature of registries and various uses for the registries, this approach could limit flexibility and stymie development of registries, forcing current innovation into a one-size-fits all registry approach. It is unclear how the directive in this legislation would fit in with the existing, extensive stake-holder developed User Guide published by AHRQ, or with the AMA's NQRN process and Council.