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ONE HUNDRED FOURTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
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MEMORANDUM

December 7, 2015

To: Subcommittee on Health Democratic Members and Staff

Fr: Committee on Energy and Commerce Democratic Staff

Re: Hearing on "Examining Legislation to Improve Health Care and Treatment"

On **Wednesday, December 9th, at 10:00 a.m., in Room 2123 of the Rayburn House Office Building,** the subcommittee will hold a legislative hearing entitled, "Examining Legislation to Improve Health Care and Treatment." The subcommittee will review six bills: (1) *H.R. 921, Sports Medicine Licensure Act of 2015*; (2) *H.R. 4152, Cardiac Arrest Survival Act of 2015*; (3) *H.R. 3441, Accurate Education for Prenatal Screenings*; (4) *H.R. 1209, Improving Access to Maternity Care*; (5) *H.R. 2713, Title VIII Nursing Workforce Reauthorization Act*; (6) *H.R. 4153, Educating to Preventing Eating Disorders Act of 2015*.

I. H.R. 921, THE SPORTS MEDICINE LICENSURE CLARITY ACT OF 2015

H.R. 921, The Sports Medicine Licensure Clarity Act of 2015, which was introduced by Rep. Guthrie (R-KY), Rep. Richmond (D-LA) and Rep. Womack (R-AR), would clarify certain aspects of medical liability and medical malpractice insurance for sports team physicians or athletic trainers who treat athletes during competitions outside of their home state.

As written, the bill deems that any medical malpractice incident occurring under the care of a traveling team physician or athletic trainer would come under the sole jurisdiction of the medical provider's primary state of practice, rather than the state in which the game was played. Additionally, the bill clarifies that for the purpose of a provider's malpractice insurance coverage, any incident that occurs while treating an athlete out of state will be deemed for insurance purposes to have occurred in the state in which the medical provider maintains their primary licensure. For example, if a team doctor holds a medical license to practice in New Jersey but travels to another state to provide care at a sporting event, any medical malpractice

event will be deemed as occurring in New Jersey, regardless of the state wherein the game was played.

Under current law, acts of medical malpractice generally fall under the jurisdiction of the state in which the incident occurred.[1] Accordingly, individual states utilize varying approaches to medical liability with regards to damage award caps, statutes of limitation, expert witness standards and a myriad of other factors.[2] In addition, individual States are autonomous in other aspects of medical care, such as requirements for medical licensure and regulation of state medical liability insurance marketplaces.

Supporters of the bill maintain it is necessary because many medical liability insurance carriers do not provide coverage for medical care provided outside of the state in which the provider is licensed.[3] Thus, many traveling physicians have difficulty maintaining adequate insurance coverage while they travel throughout the sporting season. Opponents, on the other hand, are concerned that the bill could preempt several aspects of individual state laws including tort law, court rules of procedure, and regulation of health professionals. These opponents recommend additional clarifying language, some of which is partly motivated to preserve current state laws.

Notably, the medical licensure aspect of the bill is expected to have minimal practical effect and consequences. According to the Federation of State Medical Boards, states have previously recognized that multi-state licensure is an impractical hurdle for traveling sports physicians. Thus, state licensing boards have allowed the care either by providing licensure exceptions for visiting sports medicine providers or deeming that sports medicine does not fulfill the definition of "the practice of medicine" during the game.[4]

H.R. 921 presently has 98 bipartisan co-sponsors. A related Senate companion bill, S. 689, as introduced by Sen. Thune (R-SD) has been introduced and referred to the Senate Health, Education, Labor, and Pensions Committee.

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[1] Congressional Research Service, *Medical Malpractice: Overview and Legislation in the 112th Congress* (June 18, 2012) (online at http://www.crs.gov/Reports/R41693?source=search&guid=dbd90ee0f8fb4dd08503f75beccd0b62&index=0).

[2] National Conference of State Legislatures, *Medical Liability/Medical Malpractice Laws* (August 15, 2011) (online at http://www.ncsl.org/research/financial-services-and-commerce/medical-liability-medical-malpractice-laws.aspx).

[3] National Athletic Trainers' Association, *The Sports Medicine Clarity Act* (2015) (online at http://www.nata.org/Sports_Medicine_Licensure_Clarity_Act).

[4] Federation of State Medical Boards, *Report of the FSMB Workgroup on Innovations in State Based Licensure.* (April 14, 2014). (online at http://www.fsmb.org/Media/Default/PDF/FSMB/Advocacy/report_of_state_innovations_adopted.pdf).

II. H.R. 4152, THE CARDIAC SURVIVAL ACT OF 2015

The Cardiac Survival Act of 2015, which was introduced by Rep. Olson (R-TX) and Rep. Gerald Connolly (D-VA), would expand civil liability protections related to automated external defibrillator devices (AED). The bill would amend the Public Health Service Act to provide immunity for individuals who utilize an AED during a good faith medical emergency as well as the owners and operators of a facility that may own a publically available AED.

According to the American Heart Association, approximately 326,200 Americans suffer from out-of-hospital cardiac arrest each year.[5] Oftentimes, this is caused by an abnormal rhythm of the heart called "ventricular fibrillation" which can be reversed by the use of an AED. Prompt use of AEDs is important, since studies have shown that survival decreases by 7-10 percent for every minute delayed until defibrillation.[6] According to the Institute of Medicine, public access defibrillators have been found to improve survival rates of out-of-hospital cardiac arrest (OHCA) when deployed in federal buildings, airports, casinos, fitness centers, churches, schools and workplaces.[7] Despite these successes, less than 4 percent of Americans with OHCA are treated by a bystander with an AED.[8]

In 2000, civil liability protections for lay persons who utilize AED's were first granted as "Good Samaritan Laws" under the Cardiac Arrest Survival Act.[9] This law provided protections from lawsuits for a Good Samaritan or building owner that acts in good faith to purchase or use an AED during the attempt to save a life. Of note, the federal law does not preempt state laws related to AED civil protections. According to the National Conference of State Legislatures, as

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[5] Mozaffarian D, et al., *Heart Disease and Stroke Statistics –2015 Update.* Circulation. (2015). 131:00-00. (online at http://circ.ahajournals.org/content/early/2014/12/18/CIR.0000000000000152).

[6] Valenzuela, TD, et al. *Estimating Effectiveness of Cardiac Arrest Interventions.* Circulation (1997). 96:3308-3313. (online at http://circ.ahajournals.org.proxy-um.researchport.umd.edu/content/96/10/3308.long).

[7] Graham R, et al. *Strategies to Improve Cardiac Arrest Survival: A Time to Act* (2015) IOM Institute of Medicine. Washington, DC: The National Academies Press.

[8] McNally B, et al. *Out-of-Hospital Cardiac Arrest Surveillance --- Cardiac Arrest Registry to Enhance Survival (CARES), United States, Oct 1, 20015 – December 31, 2010.* Center for Disease Control and Prevention. MMWR. (July 29, 2011). 60(SS08);1-19. (online at http://www.cdc.gov/mmwr/preview/mmwrhtml/ss6008a1.htm).

[9] *See* Pub. L. No. 106-505.

of 2012, the majority of states had passed laws that allow lay persons to use AEDs and provide varying degrees of immunity protections.[10]

Proponents of the bill aim to promote AED usage by decreasing a perceived risk of liability by an OHCA bystander. While this is one concern cited by the IOM, several additional factors appear to contribute to low rates of bystander defibrillation.[11] Limited public knowledge of AED usage, low rates of training, limited device access and inaccessible storage are all noted by the IOM as contributing factors for low rates of public defibrillation.

Opponents of the bill believe that the measure is both redundant and may produce unintended consequences. As noted above, all states have some form of Good Samaritan protection for AED usage under current law. However, under the bill's language, some have argued the bill would improperly expand legal immunity to the owners of an AED even if the owners were not following state law, which effectively preempts state law.

III. H.R. 3441, THE ACCURATE EDUCATION FOR PRENATAL SCREENINGS ACT

A. Background

A cell-free DNA prenatal screening is a screening test for fetal aneuploidy or the presence of an abnormal number of chromosomes.[12] These tests are also referred to as noninvasive prenatal screening (NIPS), noninvasive prenatal testing (NIPT), and noninvasive prenatal diagnosis (NIPD). Being laboratory-developed tests, these tests are not currently approved or cleared by the Food and Drug Administration (FDA) prior to coming to market. These tests use a blood sample from a pregnant woman to detect certain genetic conditions during pregnancy based on the cell-free fetal DNA in the plasma of the pregnant women.[13]

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[10] National Conference of State Legislatures, *State Laws on Cardiac Arrest and Defibrillators* (January 31, 2015) (online at http://www.ncsl.org/research/health/laws-on-cardiac-arrest-and-defibrillators-aeds.aspx).

[11] Graham R, et al. *Strategies to Improve Cardiac Arrest Survival: A Time to Act* (2015) IOM Institute of Medicine. Washington, DC: The National Academies Press.

[12] American College of Obstetricians and Gynecologists and the Society for Maternal-Fetal Medicine, *Committee Opinion on Cell-free DNA Screening for Fetal Aneuploidy*, (Sept. 2015) (online at http://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Genetics/Cell-free-DNA-Screening-for-Fetal-Aneuploidy).

[13] *Noninvasive Prenatal Screening*, Genetics Engineering and Biotechnology News (Nov. 11, 2015).

These tests first became commercially available in 2011 for high-risk pregnancies.[14] However, these tests are now used in both high risk and general obstetric populations. The results of cell free DNA prenatal screening tests are reported in various ways such as either a positive or negative aneuploidy risk or the chance of aneuploidy.[15] While some types of these tests may be used to detect sex chromosomes and other chromosome abnormalities, all laboratories that currently offer cell-free DNA screening include screening for trisomy 13 (the very rare Patau Syndrome), trisomy 18 (the rare Edwards Syndrome) and Trisomy 21 (Down syndrome).[16]

It is important to note and to understand that these are screening tests so they do not provide an actual diagnosis. Additionally, these tests can result in false positives and false negatives as well as an indeterminate results. A woman would have to have a diagnostic test, such as an amniocentesis, to obtain a reliable diagnosis.

A recent investigation into these types of tests highlighted a number of other issues and shortcomings, including companies claiming high accuracy rates without appropriate validation, as well as a lack of understanding among parents and doctors regarding the limitations and risks associated with such tests. Marketing claims for these types of tests cite very high accuracy rates, with one company claiming a specificity of 99.9 percent for trisomy 18, and 99.95 percent for triosomy 13,[17] and another company claiming a "very low false-positive rate."[18] Further, companies have not made clear to patients and doctors that follow-up testing for confirmation is needed as trisomy18 and 13 are so rare that high false-positive rates are common. As a result, some patients have relied on their tests results as a diagnosis rather than obtaining further diagnostic or confirmation testing, or receiving appropriate genetic counseling. Several press reports have detailed some of the harmful consequences that have resulted.[19] FDA also recently

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[14] *Supra* note 12; Devers, Patricia, et al., *Noninvasive Prenatal Testing/Noninvasive Prenatal Diagnosis: the Position of the National Society of Genetic Counseling*. J Genet Counsel. (Jan. 2013).

[15] *Supra* note 12.

[16] *Id*.

[17] Illumina. Verifi™ prenatal test. 2014. (online at http://www.illumina.com/clinical/reproductive-genetic-health/healthcare-professionals/non-invasive-prenatal-testing.html).

[18] Sequenom. MaterniT21 Plus. 2014. (online at https://laboratories.sequenom.com/providers/maternit21-plus/. Accessed December 7, 2014).

[19] See, e.g., *Oversold prenatal tests spur some to choose abortions*, Boston Globe (Dec. 14, 2014).

cited issues with noninvasive prenatal tests yielding both false-positive and false-negative results.[20]

Another concern regarding the tests is that all of the information available about this tests, including marketing claims and accuracy rates, are produced by the manufacturers of the tests. FDA does not evaluate manufacturer claims or review the tests to determine if they are analytically or clinically valid.

Further, some stakeholders have also expressed concern that accurate and up-to-date information regarding the conditions these tests screen for is not provided to patients or providers.

B. Summary of the "Accurate Education for Prenatal Screenings Act"

H.R. 3441 was introduced by Rep. Jaime Herrera Beutler (R-WA) and Rep. Lucille Roybal-Allard (D-CA) on August 4, 2015. This legislation would direct the Centers for Disease Control and Prevention (CDC) to establish a patient education program and a provider education program on cell-free DNA prenatal screenings within one year of enactment. The CDC would have to develop educational materials on these tests and the conditions that the cell-free DNA prenatal screenings test for these programs and materials are intended to fill in the gaps that CDC identifies in existing materials and programs.

Concerns have been raised about whether federal legislation is needed at this time to address patient and provider education regarding these tests. The House Appropriations Committee Fiscal Year 2016 Labor-HHS Appropriations bill requests a report on how CDC and other HHS agencies are ensuring patients and providers understand the accuracy and meaning of screening results and tested-for conditions, limitations of the results and screenings, and appropriate follow-up communication. The report would also look at CDC's role in developing materials to help support better understanding and how CDC could work with private organizations on these issues. Further, the Perinatal Quality Foundation (PQF), a non-profit foundation focused on maternal fetal medicine, is currently in the process of developing an education program on cell-free DNA for providers and patients. Questions have also been raised as to whether CDC is the appropriate federal agency to develop and implement an education program regarding these tests. It is also important to note that H.R. 3441 would require CDC to utilize existing resources to develop, implement, and maintain the patient and provider education programs.

IV. H.R. 1209, THE IMPROVING ACCESS TO MATERNITY CARE ACT

A. Background

The National Health Service Corps (NHSC) places health care providers in community-based settings in medically-underserved communities to expand access to primary health, dental

[20] FDA, "The Public Health Evidence for FDA Oversight of Laboratory Developed Tests: 20 Case Studies," (November 16, 2015)

health, and mental health services. The NHSC achieves this goal by providing scholarships and student loan repayment to NHSC members in exchange for providing services in medically-underserved communities. Health Resources and Services Administration (HRSA) administers the NHSC program and determines which communities are eligible for the placement of NHSC members through the use of three health professional shortage area (HPSA) designations: Primary Care HPSAs, Dental HPSAs, and Mental Health HPSAs. The HSPA designations are determined by specific provider to population ratios.

The Primary Care HPSA currently includes obstetrics and gynecology health services within the types of primary health care services delivered by NHSC members. Therefore, physicians specializing in Obstetrics and Gynecology (OB/GYN), Certified Nurse Midwives (CNMs), Nurse Practitioners (Women's Health), and Physician Assistants (Women's Health) currently can and do participate within the NHSC program in communities with a shortage of primary care providers.

B. Summary of the "Improving Access to Maternity Care Act"

H.R. 1209 was introduced by Rep. Michael Burgess (R-TX), Rep. Lois Capps (D-CA), and Rep. Tammy Duckworth (D-IL) on March 3, 2015. It is our understanding that the goal of this legislation is to expand access to maternity care services by creating a new designation within the Primary Care HPSA to specifically designate communities that have a shortage of maternity care providers. The creation of a specific Maternity Care HPSA designation within the Primary Care HPSA designation would allow HRSA to identify what constitutes a shortage of providers of full scope maternity care health services and designate geographic areas accordingly. Full scope maternity care health services are defined in the bill as labor care, birthing, prenatal care, and postpartum care.

While some data is available, such as the lack of certain types of maternity care providers by county and published reports on women being unable to access prenatal care, there currently does not exist a mechanism to determine what constitutes a shortage of maternity care providers in a geographic area. Data analysis resulting from efforts to establish this designation could fill these gaps and help to improve our ability to ensure that women have adequate access to maternity care services. The Maternity Care HPSA could also allow HRSA to better target the providers of obstetrics and gynecology services within the NHSC to areas with the most need.

One question that has been raised about the legislation is whether it would result in NHSC members being placed in inpatient settings and, if so, whether this would hinder our ability to expand access to community-based primary care providers through the NHSC. Currently NHSC members are not placed in inpatient settings and instead serve in community-based settings such as Federally Qualified Health Centers (FQHCs).

V. H.R. 2713, TITLE VIII NURSING WORKFORCE REAUTHORIZATION ACT OF 2015

A. Background

Title VIII of the Public Health Service Act established federal nursing workforce development grant programs that are administered by HRSA. Those programs focus on nursing education, practice, recruitment, and retention. Examples of those programs include Advanced Nursing Education Grants; Nursing Workforce Diversity Program; NURSE Corps Loan Repayment and Scholarship Program; Nurse Faculty Loan Program; Comprehensive Geriatric Education Program; Advanced Education Nursing Traineeships and Nurse Anesthetist Traineeships; and the Nurse Education, Practice, Quality, and Retention Program. Title VIII also established a National Advisory Council on Nurse Education and Practice. Title VIII nursing workforce programs have long enjoyed bipartisan support in Congress, and continued investment in these programs will help ensure that our nation has an adequate nursing workforce.

B. Summary of the "Title VIII Nursing Workforce Reauthorization Act of 2015"

H.R. 2713 was introduced by Rep. Lois Capps (D-CA) and Rep. David Joyce (R-OH) on June 10, 2015. This legislation would reauthorize Title VIII nursing workforce programs through 2020. H.R. 2713 would also make technical changes to the statute to reflect advancements in the field of nursing. The legislation would add the definition of nurse-managed health clinic to the Title VIII statute. The legislation would also amend the Advanced Education Nursing Grants and the National Advisory Council on Nurse Education and Practice to include clinical nurse specialists. This change is needed to incorporate all four of the current roles of advanced practice registered nurses into those sections; currently only nurse practitioners, nurse midwives, and nurse anesthetists are included. Finally, the legislation would further amend the Advanced Education Nursing Grants to include clinical nurse leaders to incorporate advance education programs that train nurses to serve in this relatively new nursing role.

VI. H.R. 4153, EDUCATING TO PREVENT EATING DISORDERS ACT OF 2015

A. Background

According to the Alliance for Eating Disorders Awareness, eating disorders currently affect approximately 25 million Americans.[21] While eating disorders mostly affect women, approximate 25 percent of those currently suffering from eating disorders are male.[22] Eating disorders frequently present during the teen years or young adulthood.[23] Eating disorders include extreme emotions, attitudes and behaviors surrounding weight and food issues.[24] Examples of

[21] Alliance for Eating Disorders Awareness, *What Are Eating Disorders*, (online at http://www.allianceforeatingdisorders.com/portal/what-are-eating-disorders#.VmSW87grKM8).

[22] *Id*.

[23] National Institutes of Health, *Eating Disorders*, (online at http://www.nimh.nih.gov/health/topics/eating-disorders/index.shtml).

[24] National Eating Disorders Association, *Types and Symptoms of Eating Disorders*, (online at http://www.nationaleatingdisorders.org/types-symptoms-eating-disorders).

eating disorders include anorexia nervosa, binge eating disorder, bulimia nervosa, and other specified feeding or eating disorders.[25] Eating disorders can have severe consequences such as abnormally slow and/or irregular heartbeat, muscle loss and weakness, dehydration and kidney failure, and bone density loss.[26]

B. Summary of the "Educating to Prevent Eating Disorders Act of 2015"

H.R. 4153 was introduced by Rep. Renee Ellmers (R-NC), Rep.Yvette Clarke (D-NY), Rep. Kathy Castor (D-FL), Rep. Ileana Ros-Lehtinen (R-FL), and Rep. Nita Lowey (D-NY) on December 2, 2015. This legislation would create a pilot program to test the effect of early intervention on eating disorders.

This 3-year pilot program, which would be administered by the Agency for Healthcare Research and Quality (AHRQ), would provide grants to schools that serve students in grades sixth through eighth to develop best practices assessing, recognizing, and responding to students with eating disorders. The pilot would provide funding for schools to hire a health care provider to implement best practices and provide information and training to teachers and parents on recognizing the symptoms of eating disorders. The pilot would also be used to understand better how to seek help and intervention for a student with an eating disorder. H.R. 4153 would require each school that receives a grant to evaluate and report the results of their pilot program to the Department of Health and Human Services (HHS) and require HHS to post the aggregate results of the pilot on the AHRQ website.

VII. WITNESSESS

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[25] *Id*.

[26] Alliance for Eating Disorders Awareness, *Health Complications,* (online at http://www.allianceforeatingdisorders.com/portal/health-complications-anorexia#.VmSYmLgrKM8).

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