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ONE HUNDRED FOURTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115

Majority (202) 225-2927
Minority (202) 225-3641

MEMORANDUM

November 2, 2015

To: Subcommittee on Health Democratic Members and Staff

Fr: Committee on Energy and Commerce Democratic Staff

Re: Subcommittee on Health Markup of seven bills

On Tuesday, November 3, 2015, the Health Subcommittee will convene at 3:00 p.m. in room 2322 of the Rayburn House Office Building for opening statements. The Subcommittee will reconvene on **Wednesday, November 4, 2015, at 10:00 a.m. in room 2123 of the Rayburn House Office Building** to hold a markup of the following seven bills: (1) H.R. 2017, the Common Sense Nutrition Disclosure Act of 2015, and an amendment in the nature of a substitute to H.R. 2017; (2) H.R. 2446, To amend title XIX of the Social Security Act to require the use of electronic visit verification for personal care services furnished under the Medicaid program, and an amendment in the nature of a substitute to H.R. 2446; (3) H.R. 2646, the Helping Families in Mental Health Crisis Act; (4) H.R. 3014, the Medical Controlled Substances Transportation Act; (5) H.R. 3537, the Synthetic Drug Control Act of 2015; (6) H.R. 3716, the Ensuring Terminated Providers Are Removed from Medicaid and CHIP Act; and (7) H.R. 3821, the Medicaid Directory of Caregivers Act.

The Subcommittee held a legislative hearing on H.R. 2017 on June 4, 2015. The Subcommittee held a legislative hearing on H.R. 2646 on June 16, 2015. The Subcommittee held a legislative hearing on H.R. 3716 and H.R. 2446 on September 11, 2015. The Subcommittee held a legislative hearing on H.R. 3821 on September 18, 2015. The Subcommittee held a legislative hearing on H.R. 3014 and H.R. 3537 on October 8, 2015. For more information on these bills, please refer to the hearing memos found here.

Additional information will be provided if amendments in the nature of a substitute are introduced.

I. H.R. 2017, the "Common Sense Nutrition Disclosure Act of 2015", and an amendment in the nature of a substitute to H.R. 2017

The markup will consider an amendment in the nature of a substitute (AINS) to H.R. 2017, the "Common Sense Nutrition Disclosure Act of 2015," offered by Congresswoman McMorris Rodgers (R-WA).

A. Changes Made by the AINS to H.R. 2017 and Their Effects on Covered Entities, Covered Menu Items, Nutritional Labeling Compliance Dates, and Pre-emption of Civil Lawsuits and State Implementation of Labeling Requirements

The revised definition of 'restaurant or similar retail food establishment' has been removed. As originally drafted, H.R. 2017 proposed narrowing the definition of the term 'restaurant or similar retail food establishment' to a retail food establishment that derives 50 percent or more of their total revenue from the sale of food for immediate consumption or prepared and processed on site. This new definition would have the practical effect of exempting some retail food establishments, including some grocery stores and convenience stores. By removing this definition, the AINS eliminates this carve-out.

The scope of menu items subject to calorie labeling (defined as "standard menu items") would be narrowed to menu items "with the same recipe prepared in substantially the same way with substantially the same food components that … is routinely included on a menu or menu board or routinely offered as a self-service food or food on display at 20 or more locations doing business under the same name." Thus, rather than all items routinely on the menu being subject to the menu labeling requirement (as under the FDA final rule), only those menu items routinely offered in at least 20 locations with the same recipe are subject to the menu labeling requirements. Under this change, covered establishments can make minor alterations to their standardized recipes and avoid menu labeling requirements. Items that appear fewer than 60 days per calendar year on a menu are already excluded from the menu labeling requirement under the FDA final rule.

Calorie information would only have to be provided on one menu or menu board in a covered restaurant or retail food establishment, rather than, as FDA's final rule requires, on all menus and menu boards from which a customer could order food. This information would also not have to be provided on any off-site menus, such as menu flyers offering home delivery.

Additionally, if a majority of the restaurant/establishment's orders are placed remotely (e.g., by phone or internet), it can provide the information exclusively on a remote-access menu such as through a website. Thus, even if 49 percent of an establishment's revenue came from customers ordering from menu boards inside the establishment, those boards would not have to provide any calorie information.

Covered establishments would also be allowed to provide calorie information per serving size determined by the establishment, so long as they included the number of servings in the menu item. This option would be in addition to the two options already allowed in the FDA final rule: calories per whole menu item (e.g., pizza pie), or calories per discrete serving unit (e.g.,

pizza slice) so long as the total number of serving units in the standard menu item is also listed. Serving sizes are difficult to compare between foods, and often do not reflect what a person actually eats as a serving. In fact, serving sizes are often set at sizes much smaller than what a person typically consumes, which wrongly suggests that people will consume fewer calories than is usual.

Restaurants and retail food establishments would also be allowed to provide calorie information for variable menu items – those that come in different flavors, varieties, or combinations, but are listed as a single menu item (such as ice cream, pizza, or doughnuts) – in ranges, averages, individual labeling of flavors or components, or labeling of a present standard build (the version of a menu item most commonly ordered by consumers).

Covered restaurants and retail food establishments would no longer have to provide FDA, upon request, with certifications or signed statements by responsible individuals certifying that they are in compliance with the menu labeling requirements, removing a mechanism by which FDA could help ensure that someone at each establishment is taking responsibility for complying with the menu labeling requirements.

The AINS also shields covered establishments from any civil lawsuits (except those brought by federal or state governments) for not complying with federal menu labeling requirements. It also shields establishments not subject to the menu labeling requirements (e.g., because they are not part of a chain with 20 or more locations) from civil lawsuits for not complying with state menu labeling requirements to which they are subject. Further, the AINS would preempt the ability of States and localities to implement nutrition labeling requirements.

Finally, the compliance date for the menu labeling requirements would be further extended until two years after the promulgation of final regulations pursuant to the Common Sense Nutrition Disclosure Act of 2015. Meaning, the requirements would not be able to go into effect until after this legislation was enacted, regulations promulgated and finalized, and a two year compliance period. The menu labeling requirements were enacted as a part of the Affordable Care Act, passed in March 2010, giving covered establishments more than six years to prepare for the requirement to provide calorie information.

II. H.R. 2446, To amend title XIX of the Social Security Act to require the use of electronic visit verification for personal care services furnished under the Medicaid program, and an amendment in the nature of a substitute to H.R. 2446

The AINS updates an earlier legislative version of H.R. 2446, which requires states to have in place a system for the electronic verification of visits conducted as part of personal care services.

Personal care services (PCS) provide assistance to the elderly, people with disabilities, and individuals with chronic or temporary conditions so that they can remain in their homes and communities. PCS are currently offered as either a State plan optional benefit or through various demonstrations and waivers in all 50 States.

The AINS would require that if a state does not have an electronic visit verification system for PCS in place by January 1, 2018, then that state's Federal Medical Assistance Percentage (FMAP) would be reduced in terms of amounts that can be expended for home and community based services. Specifically, the legislation applies a reduction to a state's FMAP for home and community based services of 0.25 percentage points in 2018 and 2019, 0.5 percentage points in 2020, 0.75 percentage points in 2021, and by a full percentage point in 2022, and for each year thereafter. The legislation specifies a minimum floor of information that must be gathered and electronically verified by any system a state chooses to put in place as well as specific matters for states to consider (e.g., minimum burden, HIPAA, best practices in use in the state) in the course of implementing the draft law. The legislation further clarifies that nothing in the legislation may be construed to limit or impede care, or beneficiary selection of caregiver, and that no particular or uniform system is required.

HHS-OIG's Office of Investigations and many State Medicaid Fraud Control Units (MFCUs) report that the increasing volume of PCS fraud has become a top concern. For instance, in August 2012, HHS-OIG completed seven statewide audits and one citywide audit of PCS payments and identified over $582 million in questioned costs.[1]

HHS-OIG has published an extensive body of work examining Medicaid PCS, and has found significant and persistent compliance, payment, and fraud vulnerabilities.[2] These vulnerabilities demonstrate the need for CMS to take a more active role with States to combat these issues. An electronic visit verification system (EVV) is one strategy. As emphasis on deinstitutionalization grows, so too does the need for PCS in Medicaid, which is the majority payer of long-term care services. For example, in 2011, Medicaid costs for PCS totaled approximately $12.7 billion, a 35-percent increase from 2005.[3]

A full review of CMS's efforts in this area and HHS-OIG's body of recommendations is warranted. Further discussion and consideration of the AINS penalty structure is also warranted, given the lack of additional financial assistance to states on the front end to establish an EVV system, and which does little to help them narrow pre-existing administrative priorities or increase minimal support in state Medicaid programs.

III. H.R. 2646, the "Helping Families in Mental Health Crisis Act"

TITLE I – Assistant Secretary for Mental Health and Substance Use Disorders

This title would create a new Assistant Secretary for Mental Health and Substance Use Disorders position within HHS. The Assistant Secretary would be a Senate-confirmed position

[1] *Id.*

[2] Department of Health and Human Services (HHS), Office of the Inspector General (OIG), *Personal Care Services: Trends, vulnerabilities and recommendations for improvement* (November 2012) (OIG-12-12-01).

[3] *Id.*

and report directly to the Secretary of HHS. Among other requirements, the legislation would require the Assistant Secretary to be a physician or clinical psychologist.

The legislation would eliminate the current Substance Abuse and Mental Health Services Administration (SAMHSA).

All SAMHSA duties and authorities, including grant-making, would be transferred to the Assistant Secretary within 6 months of enactment. The legislation would limit the Assistant Secretary's grant-making authority to cover only those programs and activities that use evidence-based or emerging evidence-based best practices.

The legislation would establish additional duties and authorities for the Assistant Secretary. The Assistant Secretary would oversee and coordinate all HHS programs and activities related to the prevention, treatment, or rehabilitation of/for mental health and substance use disorders, mental health parity, and reduction of homelessness among individuals with mental illness. In addition, the Assistant Secretary would carry out any HHS function to improve treatment services and prevention services; ensure access to effective, evidence-based treatment for individuals with mental illness or substance use disorder; ensure grant programs adhere to scientific standards; and develop and implement initiatives to encourage individuals to pursue mental health careers focused on the treatment of individuals with severe mental illness. The legislation would require the Assistant Secretary to prioritize workforce development in addition to the integration of services, early diagnosis, and interventions in carrying out those additional authorities.

The legislation would require the Assistant Secretary to issue various reports covering matters such as mental health parity investigations; best practices for peer-support specialist programs, training, and certification; and the state of the states in mental health and substance abuse treatment. The Assistant Secretary would be required to release a nationwide strategy for increasing the psychiatric workforce and recruiting medical professionals for the treatment of individuals with serious mental illness and substance use disorders. The legislation would require the Assistant Secretary to contract with the Institute of Medicine to issue a report within 12 months of enactment evaluating the combined paperwork burden on community mental health centers and federally qualified community mental health clinics.

TITLE II – Grant Reform and Restructuring National Mental Health Policy Laboratory

The legislation would create a National Mental Health Policy Laboratory (NMHPL) within the Office of the Assistant Secretary. The legislation would establish the staffing composition of the NMHPL, including a requirement that the greater of 20 percent of or two staff members of the NMHPL be appointed by Congress. Among its other responsibilities, the NMHPL would be tasked with identifying and implementing policy changes likely to have the most significant impact on mental health services; evaluating and disseminating to grantees evidence-based practices and service delivery models; and issuing a biennial report on the quality of care furnished through grant programs administered by the Assistant Secretary. The legislation would require the Assistant Secretary to comply with standards established by the NMHPL for grant programs administered by the Assistant Secretary.

New Mental Health Grant Programs and Limited Extension of AOT Programs

The legislation would create several new mental health grant programs that would be funded through a tap on SAMHSA's general authorization as well as mental health and substance abuse programs of regional and national significance (PRNS). Those programs include Innovation Grants, Demonstration Grants, and Crisis Intervention Grants. The cumulative impact of these taps would be a 20 percent reduction in funding for PRNS and SAMHSA's general account. This means that the legislation would take funding from substance abuse programs (and existing mental health programs) to pay for the new mental health grant programs.

The Innovation Grant Program would award funding for expanding models that either enhance the screening, diagnosis, and treatment of mental illness or integrate or coordinate physical, mental health, and substance use services that have been scientifically demonstrated to show promise, yet would benefit from further applied research. This program would be funded by a 5 percent tap of PRNS and SAMHSA's general account.

The Demonstration Grant Program would award funding for expanding evidence-based programs to enhance effective screening, early diagnosis, intervention, and treatment with respect to mental illness. This program would be funded by a 10 percent tap of PRNS and SAMHSA's general account.

The legislation would authorize a Crisis Intervention Grant Program to provide crisis intervention grants to train police officers and first responders how to intervene with individuals with mental illness. This grant program would be funded by a tap of 5 percent of PRNS and SAMHSA's general account.

This legislation would amend the Protecting Access to Medicare Act to extend the authorization for the assisted outpatient treatment (AOT) grant program from FY 2018 to FY 2020 and increase the authorization of appropriations from $15 million to $20 million per year. The legislation would also require that 20 percent of funding for the AOT grant program be allocated to existing programs and 80 percent to new programs.

Community Mental Health Block Grant

The legislation would establish new requirements for states to be eligible for the Community Mental Health Block Grant (MHBG). The title would require states, in order to receive MHBG funding, to have in effect a law that provides for involuntary outpatient treatment that requires individuals to obtain outpatient mental health treatment (AOT laws) and laws that require a civil court to order involuntary inpatient or outpatient treatment for an individual if the court finds that an individual, as a result of a mental illness, is a danger to self or others, "is persistently or acutely disabled, or is gravely disabled and in need of treatment" (Treatment Standard laws). The legislation would also increase by 2 percent the MHBG allotment amount for states that have in effect AOT laws or Treatment Standard laws. The legislation also would require states to have programs in place, including AOT laws, for the active outreach and engagement of individuals with serious mental illness.

The legislation would add new requirements of what must be included in state plans detailing the use of MHBG funds for comprehensive community-based mental health services for children with serious emotional disturbance and adults with serious mental illness. Among the requirements would be a plan for the integration of primary and behavioral health care, a detailed list of services available in each county, and de-identified information about certain patients receiving treatment under the MHBG. The legislation would require a five (5%) percent set-aside of the MHBG for the Secretary, acting through the Director of the National Institute of Mental Health (NIMH), to translate evidence-based medicine into clinical care models.

Creation of Early Childhood and Intervention Grant

The legislation would also create the Early Childhood and Intervention Grant that would award grants for early childhood programs aimed at preventing chronic and serious mental illness and to entities for studying the longitudinal outcomes of those early childhood programs. This program would be funded by a five (5%) percent set-aside of the MHBG for children with serious emotional disturbance from FY 2016 to FY 2021.

Authorization of Workforce Development Grant programs

The legislation would authorize several grant programs for workforce development. The legislation would authorize a Telepsychiatry and Primary Care Physician Training Grant program to award 10 states grants to carry out all of the following: a training program for primary care physicians, payments for mental health services provided by certain primary care physicians, and telehealth services for mental health disorders. The legislation would authorize the Minority Fellowship Program (MFP) at a funding level of $6 million which is less than the $10.669 million the MFP received in FY 2015. The MFP provides funding for individuals from underserved minority populations to obtain graduate degrees in mental health professions. SAMHSA currently administers the MFP under SAMHSA's PRNS authorities.

Reauthorization of Existing Grant Programs

The legislation would amend certain definitions under the National Health Service Corps (NHSC) with the intent to allow child and adolescent psychiatry residents to participate in the NHSC Loan Repayment Program.

The legislation would authorize the National Suicide Prevention Lifeline Program (Lifeline) at a funding level of $8 million. The Lifeline is a 24-hour, suicide prevention hotline. SAMHSA currently administers the Lifeline under SAMHSA's PRNS authorities.

This title would reauthorize programs that have broad bipartisan support, including the Garrett Lee Smith Suicide Prevention Program and the National Child Traumatic Stress Initiative (NCTSI). However, the legislation would make concerning changes to both programs. The legislation would reauthorize the NCSTI for FY 2014 through FY 2018 at $45.713 million which is less than the $45.887 million the NCSTI received in FY 2015.

The legislation would reauthorize the Garrett Lee Smith Act grant programs for FY 2016 through FY 2020. This includes the Suicide Prevention Technical Assistance Center Grant Program at $4.957 million (which is less than the $5.988 million the program received in FY 2015), the Youth Suicide Early Intervention and Prevention Strategies Grant Program at $29.738 million and the Mental Health and Substance Use Disorders Services on Campus Grant Program at $4.975 million (which is less than the $6.488 million it received in FY 2015).

Within the language reauthorizing the Garrett Lee Smith Act grant programs, the legislation contains an abortion prohibition. Under current law, the three Garrett Lee Smith Act grant programs are prohibited from using grant funding to pay for or refer for abortion services. This legislation explicitly maintains that restriction but also extends that restriction to the SAMHSA's Projects for Assistance in Transition from Homelessness, or PATH, Program. The PATH Program is a formula grant program to the 50 states, D.C., and the U.S. Territories that provides services to people with serious mental illness who are experiencing homelessness or are at imminent risk of becoming homeless. Currently, no such restriction exists in the statutory language authorizing the PATH Program, but the Hyde restriction that is included in the annual appropriations legislation would apply. It is also important to note that this language goes beyond the Hyde language because it not only applies to the payment for abortion services but also to referring for abortion services.

Raising Student Awareness of SMI

The Secretary of Education, along with the Assistant Secretary, would be required to organize a national awareness campaign to help students reduce the stigma associated with and understand the importance of seeking treatment for serious mental illness. The campaign would target high school and college students.

Malpractice Coverage for Behavioral Health Care Workers

This legislation would extend federal malpractice liability coverage to health care professional volunteers who are providing specified services at community health centers and Federally-Qualified Community Behavioral Health Clinics.

TITLE III – Interagency Serious Mental Illness Coordinating Committee

The legislation would establish an Interagency Severe Mental Illness Coordinating Committee of Federal and non-Federal members to support the Assistant Secretary in carrying out his/her duties. The members would include 4 members who are politically appointed; one appointment each by the Speaker of the House of Representatives, the Minority Leader of the House of Representatives, the Majority Leader of the Senate, and the Minority Leader of the Senate. This could politicize the Committee. Among other duties, the Committee would have to develop, annually update, and submit to Congress a strategic plan for increasing utilization of mental health services and compliance with treatment.

Title III -- HIPAA and FERPA Caregivers[4]

This title would also make changes to current Health Insurance Portability and Accountability Act (HIPAA) provisions as they relate to provider disclosure of protected health information to family members and individuals who "assume primary responsibility" of a patient with a serious mental illness. It would provide a new exception to the HIPAA privacy rule, intended to address situations in which providers have refused to disclose information to family members regarding a patients' treatment.

Problems with applications of the rule, however, are largely attributable to provider misperceptions regarding their duties and obligations under HIPAA. HIPAA already gives providers broad discretion to share information with family members and caregivers, where doing so would aid an individual's treatment. The HHS Office of Civil Rights has recently issued guidance to clarify providers' obligations.[5] Unless a patient objects, HIPAA already provides a clear path to communicate with family.

In recognition of the important role that family members play in a patients' care, the HIPAA rule allows providers to communicate with a patients' family members or others involved in his or her healthcare, so long as the patient does not object.[6] Even if the patient does object, health care professionals can make disclosures of protected health information, if the provider has a good faith belief that the disclosure is "necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public."[7] If a patient is incapacitated, for instance due to temporary psychosis or under the influence of drugs or alcohol, and cannot meaningfully agree or object to the sharing of information with caregivers, the provider can share information with the caregivers if it would be in the patients' best interests.[8]

The legislation also would include a new exception to the privacy rules surrounding the treatment of substance abuse disorders. Under current law, there are additional protections for records pertaining to the identity, diagnosis, or treatment of patients with substance abuse disorders.[9] These laws and regulations were enacted three decades ago in recognition of the stigma associated with substance abuse and fear of prosecution that deterred people from entering treatment. For instance, providers must maintain written consent for disclosures of

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[4] HIPAA comments are included in this memo. FERPA is outside of the Energy and Commerce Committee's jurisdiction.

[5] HHS, *HIPAA Privacy Rule and Sharing Information Related to Mental Health* (February 20, 2014) (online at www.hhs.gov/ocr/privacy/hipaa/understanding/special/mhguidance.html).

[6] 45 C.F.R. 164.510(b).

[7] 42 C.F.R. 164.512(j).

[8] HHS, *HIPAA Privacy Rule and Sharing Information Related to Mental Health* (February 20, 2014) (online at www.hhs.gov/ocr/privacy/hipaa/understanding/special/mhguidance.html).

[9] 42 U.S.C. 290dd-2.

protected health information, even for the purposes of treatment or payment (which is not required under HIPAA).[10]

The new privacy regulation called for by the legislation would exempt accountable care organizations, health information exchanges, health homes, or other integrated care arrangements from existing privacy and consent requirements, for purposes of "attaining interoperability, improving care coordination, reducing health care costs, and securing or providing patient safety." Some stakeholders have expressed concern that this would open up substance abuse treatment records to hundreds and even thousands of providers, many of whom do not have a clinical relationship with the patient.

However, some providers have argued that these privacy regulations present a hurdle to the treatment of patients with substance abuse disorders, particularly in light of the movement in our healthcare system towards coordination of care and integration of mental and physical healthcare.[11] SAMHSA has solicited input from stakeholders on updating the regulations and is expected to issue proposed changes in the near future.[12]

TITLE V – Medicare and Medicaid Reforms

This section would restrict state Medicaid programs from prohibiting payment for a mental health or primary care services provided at a community mental health center or a federally qualified health center when the mental health service was received on the same day as the primary care service or vice versa.

It would eliminate the IMD exclusion in Medicaid by authorizing federal matching payment for services provided in an inpatient psychiatric residential treatment facility or psychiatric residential treatment facility for individuals ages 21 to 64, if the Chief Actuary of CMS certifies that this change would not increase federal Medicaid spending. It also would eliminate the 190-day lifetime limit on inpatient psychiatric services under Medicare if the Chief Actuary of CMS certifies that this change would not increase federal Medicare spending. It is improbable, however, that either provision would ever lead to Chief Actuary certifications since it is likely that both sets of changes would result in increased spending.

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[10] HHS, Substance Abuse and Mental Health Services Administration, *Overview of Alcohol/Drug Confidentiality Regulations- 42 C.F.R. Part 2* (online at www.integration.samhsa.gov/clinical-practice/mat/Webinars_2012_Overview_of_Alcohol_and_Drug_Confidentiality_Regulations-_42_CFR_Part_2.pdf).

[11] See, e.g., House Committee on Energy and Commerce, *Hearing on Combatting the Opioid Abuse Epidemic: Professional and Academic Perspectives*, 114th Cong. (Apr. 23, 2015).

[12] HHS, Substance Abuse and Mental Health Services Administration, *Notice of Public Listening Session*, Federal Register (May 12, 2014).

This title would make permanent the inclusion of antipsychotics and antidepressant drugs as protected drug classes under Medicare Part D. That would mean that Medicare Part D plans would have to provide all drugs within those classes.

The bill would prohibit state Medicaid programs from excluding coverage for drugs used for the treatment of a mental health disorder, including major depression, bipolar (manic-depressive) disorder, panic disorder, obsessive compulsive disorder, schizophrenia, and schizoaffective disorder. The provision explicitly applies this requirement to Medicaid managed care plans. This provision seems to protect broad classes of drugs that are used to treat a wide range of mental health conditions. For example, Adderall used for attention deficit hyperactivity disorder is considered to be a drug that can be used to treat a mental health condition, but may not be what the legislation actually intends to protect.

In addition, the bill would require the Secretary of HHS to develop and issue, through regulations, guidelines and standards for new discharge planning requirements for psychiatric hospitals.

It would also amend the two-year, eight state demonstration program to improve services provided by certified community behavioral health clinics included in the Protecting Access to Medicare Act, by extending the demonstration to four years and by increasing the maximum number of demonstration project states to ten.

TITLE VI – Research by the National Institute of Mental Health

This title would authorize $40 million a year from FY 2016 through 2020 for the National Institute of Mental Health (NIMH) -- beyond amounts currently available for the Institute -- for research on: (1) the determinants of self- and other directed-violence in mental illness; and (2) the **B**rain **R**esearch through **A**dvancing **I**nnovative **N**eurotechnologies (BRAIN) Initiative. This specific authorization of appropriations for NIMH research does not follow the standard authorization convention of just having a single, agency- wide authorization for the National Institutes of Health (NIH).

TITLE VII – Behavioral Health Information Technology

This title allows behavioral and mental health providers to receive incentive payments for the meaningful use of health information technology.

TITLE VIII – SAMHSA Reauthorization and Reforms

This title would require at least half of the members of any peer review group established to review proposals or grants to be physicians, clinical psychologists, or licensed mental health professionals. The title would require the Assistant Secretary to provide a list of peer review group members to Congress prior to awarding any grant, cooperative agreement, or contract reviewed by the group; and notify Congress 60 days before awarding any grant, cooperative agreement, or contract. The legislation would require at least half the members of each advisory

council to be mental health care providers with experience in research or treatment and in the fields on which they are advising.

While the inclusion of mental health provider perspectives on peer review groups and advisory councils seems reasonable, a rigid requirement for members with this expertise may not be feasible and may minimize the opportunity to encourage and develop important interdisciplinary perspectives. Requiring written notice to Congress before awarding any grants would be an atypical and overly burdensome task.

This title would also require the Protection and Advocacy for Individuals with Mental Illness (PAIMI) program to limit its activities and focus to abuse and neglect. Such a limitation, however, would prevent the PAIMI program from helping to protect individuals with mental illness avoid violations of, or to assert their rights, such as in instances of housing discrimination.

The legislation would also prohibit a P&A from counseling an individual with a serious mental illness on their right to refuse medical treatment and from acting against the wishes of the caregiver of an individual with severe mental illness. It would also require a P&A to ensure that caregivers of individuals with serious mental illness have access to their protected health information.

Finally, the legislation would further prohibit any Protection and Advocacy System (P&A) receiving PAIMI funds from lobbying, including with private funds.

Taken individually and collectively, these new requirements appear to realign the P&A's responsibilities and duties more closely with the interests of caregivers than with the needs and rights of individuals suffering from mental illness. These shifts in the law would in some cases even require a P&A to divert its own resources to help caregivers that unacceptably compromise the rights of individuals with mental illness without according them any corresponding benefits.

TITLE IX – Reporting

This title would require a GAO report on compliance with the Mental Health Parity and Equity Addiction Act.

IV. H.R. 3014, the "Medical Controlled Substances Transportation Act"

H.R. 3014, introduced by Representative Sessions (R-TX), would allow a physician to transport controlled substances to another practice setting or to a Presidentially-declared disaster area, if the physician is registered to dispense controlled substances listed on schedules II, III, IV, or V, and the physicians enters into a specific agreement with the DEA. The agreement would require a physician to provide advance notification to the DEA of any such transport, identify the controlled substances to be transported and the locations to and from which the controlled substances will be transported, the intended dates of transport, anticipated travel time and more. The physician is also required under the agreement to maintain records in the physician's primary practice setting on the dispensing of any controlled substance transported,

including the location and quantity. Further, the duration of such transport is limited to no more than 72 consecutive hours.

Currently, physicians are prohibited from transporting controlled substances away from their registered practice locations to other locations. This legislation would allow, for example, athletic team physicians to transport a supply of controlled substances to athletic games in other states, or physicians to bring controlled substances to respond to a disaster.

V. H.R. 3537, the "Synthetic Drug Control Act of 2015"

H.R. 3537 was introduced by Representatives Dent (R-PA), Himes (D-CT), Holmes Norton (D-DC), and Jolly (R-FL). This legislation would add a list of 316 synthetic drugs identified by DEA to Schedule I of the Controlled Substances Act (CSA), broken out into nine different classes including cannabinoids and opioids. The legislation would also make any compound that is chemically or pharmacologically similar to a controlled substance in Schedule I or II of the CSA to be legally treated as though it was listed in that same schedule. Currently, under the Controlled Substances Analogue Enforcement Act (the Analogue Act), substances must be substantially similar in chemical structure and pharmacologically similar to be considered as listed in Schedule I or II. The legislation would also narrow the Analogue Act so that it would only apply to the manufacture, importation, distribution, and sale of drugs, not possession. These changes are intended to assist with the prosecution of synthetic drug manufacturers and distributors and inhibit its use in the prosecution of people who are simply users of the drugs.

The synthetic drugs that are the target of the legislation are chemically modified versions of existing Schedule I drugs, modified to escape control by DEA while still retaining or enhancing their potential for abuse. For example, some are designed to mimic or enhance the effects of drugs such as marijuana, cocaine, or methamphetamine. The effects and potential dangers of these substances are not well known. Use of synthetic drugs is reportedly on the rise, leading some to call on Congress to legislatively schedule specific substances. In June 2012, Congress passed the Synthetic Drug Control Act of 2011, to among other things, schedule selected synthetic stimulants and other synthetic substances. Criticisms have been raised about scheduling substances legislatively, with some arguing that the current formal scheduling process is too laborious to schedule synthetic drugs, which chemists can manipulate and modify relatively quickly.

VI. H.R. 3716, the "Ensuring Terminated Providers Are Removed from Medicaid and CHIP Act"

H.R. 3716, introduced by Representatives Buschon (R-IN), Butterfield (D-NC) and Welch (D-VT) implements OIG recommendations from two reports to strengthen authorities originally authorized under the ACA to terminate providers.[13] It would require states to report

[13] The Department of Health and Human Services' Office of the Inspector General published two reports that provide the basis for the provider terminations legislation under consideration for the hearing: *CMS System for Sharing Information About Terminated Providers Needs*

the termination of any individual or entity from the state's Medicaid/CHIP program to the Secretary within 14 business days from the date of termination. The legislation sets forward specific criteria for inclusion in the report, and would apply such requirements in both the managed care and fee-for-service space, and would also apply to the CHIP program. The legislation would also require the Secretary to develop uniform technology for states to use with respects to specifying reasons for termination. The Secretary would be required to ensure that information received from states regarding terminated providers was included in the Termination Notification Database within 14 business days of receipt. Two years following enactment, the Secretary would be vested with authority to terminate payment to providers 60 days after applicable terminations have been recorded in the database.

This legislation would prescribe mandatory HHS reporting criteria and timelines in statute. However, technical fixes are needed to ensure that intent of the legislation is achieved fully, and existing provider appeal processes are preserved.

VII. H.R. 3821, the "Medicaid Directory of Caregivers Act" (Medicaid DOC Act)

H.R. 3821, introduced by Representatives Collins (R-NY) and Tonko (D-NY), requires states that participate in fee-for-service Medicaid to publish a provider directory on at least a semiannual basis. The proposed legislation stipulates several items to be included in the directory – specifically, a provider's name, the provider's specialty, and contact information. In addition, if providers participate in a primary care case management system, the directory must include whether the provider is accepting new patients, speaks any foreign languages, and whether their office is accessible by people with physical disabilities.

This proposed legislation is timely as recent reports have highlighted significant problems with provider directories in both public and private health systems.[14] Many patients have found it difficult under the current system to verify whether a particular doctor is affiliated with their health plan. For physicians, many have been unclear whether or not they have been included as part of new insurance networks as part of a state or federal health insurance exchanges. In addition, many patients have faced surprise medical bills due to confusing or misleading network directories. Even those patients who make a good faith attempt to see an in-network physician may receive out-of-network bills from other members of the care team.[15] A common example is a patient's surgeon being in-network, but the anesthesiologist is not.

Improvement (March 2014) (OEI-06-12-00031), and *Providers Terminated from One State Medicaid Program Continued Participating in Other States* (August 2015) (OEI-06-12-00030).

[14] *Enrollees at health exchanges struggle to prove coverage*, New York Times (January 10, 2014) (online at http://www.nytimes.com/2014/01/11/us/enrollees-at-health-exchanges-face-struggle-to-prove-coverage.html).

[15] *After surgery, surprise $117,000 medical bill from doctor he didn't know,* New York Times (Sept. 20, 2014) (online at http://www.nytimes.com/2014/09/21/us/drive-by-doctoring-surprise-medical-bills.html).

Another example is of a hospital listed as in-network, but an emergency department doctor who is not.

This legislation, however, would not apply to Medicaid managed care enrollees. It is important to note that many states make use of both fee-for-service and managed care in different components of their Medicaid programs, CMS's recent proposed rule for managed care strengthens the requirements related to health plan provider directories, including requiring that online directories be updated within 3 business days of a change in a provider's status and that paper directories be updated monthly.