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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
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MEMORANDUM

September 17, 2015

To: Subcommittee on Health Democratic Members and Staff

Fr: Committee on Energy and Commerce Democratic Staff

Re: Hearing on "Improving the Medicaid Program for Beneficiaries"

On Friday, September 18, at 9:00 a.m., in room 2123 of the Rayburn House Office Building, the Committee will hold a legislative hearing on four bills regarding Medicaid beneficiaries. Three of the bills maintain bipartisan support and have passed the Senate with little controversy. They are H.R. 209, which would exempt patient compensation from Supplemental Security Income (SSI) eligibility criteria for participating in a clinical trial for a rare disease or condition; H.R. 3243, which would grant the Secretary of Health and Human Services (HHS) the authority to conduct demonstration projects involving the Programs of All-Inclusive Care for the Elderly (PACE); and H.R. 670, which would allow disabled individuals to set up special needs trusts for themselves without a court petition. The fourth bill, "The Medicaid DOC Act," is draft legislation which requires states that participate in fee-for-service Medicaid to publish up-to-date provider directories.

I. BACKGROUND

Established along with Medicare by the Social Security Act of 1965, Medicaid and the CHIP program provide coverage for nearly 72 million individuals.[1] Medicaid plays a significant

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[1] Department of Health and Human Services, *Medicaid and CHIP: June 2015 Monthly Applications, Eligibility Determinations and Enrollment Report* (August 31, 2015) (online at http://www.medicaid.gov/medicaid-chip-program-information/program-information/downloads/june-2015-enrollment-report.pdf).

role for children, the disabled, and the elderly. Medicaid covers 33 million children, which accounts for over one third of the nation's children.[2]

The Medicaid program is also a critical component of care for seniors and those with disabilities.[3] One out of every 7 elderly Medicare beneficiaries is also a Medicaid beneficiary.[4] In FY 2012, elderly and disabled enrollees accounted for 21 percent and 42 percent, respectively of Medicaid expenditures. And, 200,000 additional enrollees aged 65 or older signed up for Medicaid from 2014–2015.[5] Medicaid is also the primary payer of long term services and supports (LTSS), which represented slightly more than half (51 percent) of total national LTSS spending in 2013.[6]

For further background information on the Medicaid program, please refer to the Committee's memo from July 7, 2015.

II. H.R. 209, the "Ensuring Access to Clinical Trials Act of 2015"

H.R. 209, the "Ensuring Access to Clinical Trials Act of 2015, which was introduced by Rep. Doggett (D-TX), Rep. Marino (R-PA) and Rep. McGovern (D-MA), would make permanent a change instituted in 2010, that allows people receiving SSI and Medicaid benefits to take part in clinical trials without jeopardizing their eligibility for those benefits. The 2010 law included a sunset after five years so its effects could be studied and assessed. This change to the law will sunset, unless legislation is reauthorized by October 5, 2015.

The SSI Program provides cash benefits to low-income individuals who are aged, blind or disabled. To remain eligible for the program, individuals must meet specific financial eligibility requirements for both income and resources. In 2014, an eligible individual could not possess resources amounting to more than $2,000 ($3,000 for a couple). The maximum allowable income was $721 monthly ($1,082 for a couple). Importantly, certain assets such as an individual's home or vehicle are not counted against a persons' eligibility. With regards to income, other assistance benefits such as nutrition and housing benefits are not counted against SSI disability

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[2] Kaiser Family Foundation, *Distribution of Medicaid Enrollees by Enrollment Group* (2011) (online at http://kff.org/medicaid/state-indicator/distribution-of-medicaid-enrollees-by-enrollment-group/).

[3] HHS, *FY2016 Budget in Brief: CMS Medicaid Services* (online at http://www.hhs.gov/about/budget/budget-in- brief/cms/medicaid/index.html#services).

[4] *Id.*

[5] *Id.*

[6] Kaiser Family Foundation, *Medicaid and Long-Term Services and Supports: A Primer* (May 8, 2015) (online at http://kff.org/medicaid/report/medicaid-and-long-term-services-and-supports-a-primer/).

The 2010 law allowed for a disregard of up to $2,000 of compensation per year for the purposes of SSI income eligibility that an individual receives for participation in a clinical trial investigating a rare disease or condition.[7] According to the U.S. Government Accountability Office (GAO), since this law was enacted, compensation for participating in clinical trials has been excluded for 36 SSI recipients when determining their eligibility and benefit amounts.[8] The amount of compensation disregarded for each recipient generally ranged from $50 to $2,000 each year.[9] The report also found that for rare diseases, the largest overall barriers to clinical trial participation were travel requirements and time spent during the clinical trial, especially away from work or school. A large proportion of participants indicated that reimbursement for costs incurred was important in their decision to participate.

Under federal law, a rare disease is defined as one that affects less than 200,000 individuals in the United States.[10] According to the Institute of Medicine, Americans are affected by approximately 7,000 rare diseases.[11] Because there are smaller patient populations in these instances, conducting clinical trials for rare diseases is logistically more difficult than for other conditions that are not as rare. As well as being fewer in number, patients may also be more geographically spread out with access to fewer research centers focusing on the particular disease. Additionally, practical barriers exist for an individual patient to participate in a clinical trial. Oftentimes, participation requires time away from school or work, travel, and a personal assessment to willingly undergo an experimental therapy. To defray these costs to the individual, clinical trials are allowed to reimburse patients for reasonable costs associated with participation.[12]

H.R. 209 presently has 49 bipartisan co-sponsors. The bill maintains support from a wide variety of patient, industry, academic and medical organizations, including the Cystic Fibrosis Foundation, the National Organization for Rare Diseases, several academic medical centers as well as others.[13] An identical companion bill (S. 139) was passed by the Senate via Unanimous Consent on July 16, 2015.

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[7] Congressional Research Service, *Summaries for the Improving Access to Clinical Trials Act of 2009* (June 15, 2009) (online at https://www.govtrack.us/congress/bills/111/hr2866/summary).

[8] Government Accountability Office. *Supra* (September 9, 2014) (online at http://gao.gov/assets/670/665629.pdf).

[9] *Id.*

[10] 21 U.S.C. § 360bb(a)(2).

[11] Institute of Medicine, *Rare Diseases and Orphan Products, Accelerating Research and Development* (Washington, D.C.: National Academies Press, 2010).

[12] Christine Grady. *Payment of clinical research subjects.* The Journal of Clinical Investigation (2005). 115(7):1681-87(online at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1159153/).

[13] *The Cystic Fibrosis Foundation Applauds Passage of the Ensuring Access to Clinical Trials Act of 2015 in the U.S. Senate*, Business Wire (July 16, 2015) (online at

III. H.R. 3243, "To amend title XI of the Social Security Act to clarify waiver authority regarding programs of all-inclusive care for the elderly (PACE programs)"

The Program of All-Inclusive Care for the Elderly (PACE) is a community-based long-term service and support program for dually-eligible frail elderly or disabled individuals aged 55 or older who would otherwise need a level of care offered in nursing homes.[14] The program is designed to allow nursing home eligible patients to remain in their homes and receive assistance and medical support services through adult day centers. Health care providers in the system receive a capitated monthly fee from both Medicare and Medicaid.[15] At the end of 2014, 34,413 beneficiaries had participated in 115 programs across 32 states.[16]

Overall, the PACE program has shown delivery of high quality care to beneficiaries.[17] Compared to other services, PACE has improved both overall mortality as well as pain control. Patients have rated personal satisfaction highly, and at similar levels to those receiving other home and community-based services.

PACE originated from a single program in 1971 and was expanded through federal Medicaid and Medicare waivers several times until eventually becoming recognized as a permanent provider type.[18] When PACE gained this recognition through the Balanced Budget Act of 1997, program requirements were permanently placed into federal statute. Under current law, the Secretary of HHS has authority to waive certain requirements of the Social Security Act to test innovative payment and delivery models.[19] However, the Secretary is not allowed to use this waiver authority in the PACE program due to historical provisions in existing statute.

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http://www.businesswire.com/news/home/20150716006642/en/Cystic-Fibrosis-Foundation-Applauds-Passage-Ensuring-Access#.VfbwaBFViko).

[14] Ghosh A, Orfield C, Schmitz R. *Evaluating PACE: A review of the literature.*

Mathematica Policy Research. (January 2014) (online at http://aspe.hhs.gov/sites/default/files/pdf/76976/PACELitRev.pdf).

[15] Kirsten Colellow, *Medicaid Coverage of Long-term Services and Supports*, Congressional Research Service. (December 5, 2013)

[16] National PACE Foundation. *PACE in the states* (2015) (online at http://www.npaonline.org/website/download.asp?id=1741&title=PACE_in_the_States).

[17] Arkadipta Ghosh, Cara Orfield, and Robert Schmitz. *Evaluating PACE: A review of the literature*. Mathematica Policy Research. (January 2014) (online at http://aspe.hhs.gov/sites/default/files/pdf/76976/PACELitRev.pdf).

[18] Hirth V, Baskins J, Dever-Bumba M. *Program of All-Inclusive Care (PACE): Past, Present, and Future.* J Am Med Dir Assoc. (2009). 10:155-160.

[19] Social Security Act, §1115(A)

H.R. 3243 would allow the Secretary to conduct demonstration projects that involve PACE.[20] Advocates expect that this waiver authority would be utilized to test the PACE program in individuals under the age of 55 or those at risk of soon needing nursing home care.[21] Existing statute excludes both of these patient populations from participating in the PACE program, and the Secretary does not have statutory authority to modify these or other provisions.

H.R. 3243 has 23 bipartisan co-sponsors and is identical to its Senate companion (S. 1362), which passed the full Senate by Unanimous Consent on August 5, 2015. The Congressional Budget Office (CBO) analyzed the Senate companion bill and determined that enactment of the bill would result in no significant change in direct spending.[22]

IV. H.R.____, the "Medicaid Directory of Caregivers Act" or "Medicaid DOC Act"

The Medicaid Directory of Caregivers Act 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, any foreign languages spoken by the provider, and whether the office is accessible for 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.[23] 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.[24] A common example is a patient's surgeon being in-network, but the anesthesiologist is not.

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[20] H.R. 3243

[21] National Pace Association, *PACE Innovation Act of 2015* (online at http://www.npaonline.org/website/download.asp?id=7252&title=PACE_Innovation_Act_of_2015.pdf).

[22] Congressional Budget Office, *Cost Estimate: S. 1362 PACE Innovation Act of 2015.* (July 9, 2015) (online at https://www.cbo.gov/sites/default/files/114th-congress-2015-2016/costestimate/s1362_0.pdf).

[23] *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).

[24] *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 would not apply to Medicaid managed care enrollees. It is important that any requirements put in place on the fee-for-service side of the program align with the managed care space, particularly given that many states make use of both fee-for-service and managed care in different components of their Medicaid programs. The Center for Medicare and Medicaid Services' (CMS) 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.

V. H.R. 670, the "Special Needs Trust Fairness Act of 2015"

H.R. 670 amends Medicaid law to extend the special needs trust exemption from the treatment of a trust as resources available for an individual for meeting income requirements for Medicaid coverage. Under current law, most trusts are counted as assets when determining an individual's eligibility for Medicaid.[25] However, certain exceptions exist, including a "special needs trust." This particular trust is designed to provide funding for non-elderly, disabled individuals that may be utilized for certain expenses that supplant Medicaid benefits.

In order to qualify for Medicaid, individuals must meet specific income and asset tests. Oftentimes, the allowable level of assets is quite low, sometimes as little as $2,000. For disabled individuals, the services provided by Medicaid can be insufficient and the beneficiary must spend additional money out of pocket for uncovered services. However, to pay for these services, the individual needs to retain a certain level of personal assets, which may in turn threaten their Medicaid or SSI eligibility. Special needs trusts specifically address this issue to allow individuals to retain necessary assets. Of note, special needs trusts generally include a Medicaid payback provision, wherein if the beneficiary dies, the State can recoup remaining trust funds up to the level of medical assistance benefits the state disbursed to the individual.

Under current law, special needs trusts can be established by parents, grandparents, legal guardians or a court on behalf of the disabled individual.[26] For individuals who may not have an available individual willing to establish the trust on their behalf, this can create significant logistical barriers, and financial if such an individual is forced to hire legal assistance on their behalf. Individuals may be allowed to set up a special needs trust for themselves, but only if granted permission after petitioning a court.[27] Oftentimes, this process can take several months and can incur significant legal fees for the disabled individual in the process. H.R. 670 would allow individuals to set up special needs trusts for themselves without a court petition.

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[25] Center for Medicare and Medicaid Services, *Letter to State Medicaid Directors* (February 21, 2014) (online at http://www.medicaid.gov/Federal-Policy-Guidance/Downloads/SMD-14-001.pdf).

[26] Social Security Act, Section 1917(d)(4)(A).

[27] Senate Committee on Finance, *Special Needs Trust Fairness Act of 2015,* 114th Cong. (July 30, 2015) (S. Rept. 114-99) (online at https://www.congress.gov/114/crpt/srpt99/CRPT-114srpt99.pdf).

The bill enjoys bipartisan support with 14 co-sponsors. An identical Senate companion bill (S. 349) passed the Senate by Unanimous Consent on September 9, 2015.

CBO performed a cost estimate of S. 349.[28] The CBO determined that over a ten year period from 2016-2025 the bill would increase direct spending by a total of $8 million. Of this, $5 million is a result of additional months of Medicaid coverage and $3 million is an additional months of SSI benefits. The CBO estimated a small population of individuals would be affected by the bill. The modest costs come from the decreased administrative burden that allows the affected individuals to access SSI benefits sooner than if they were required to petition the courts.

VI. WITNESSES

Michael Boyle, M.D.
Vice President of Therapeutics Development
The Cystic Fibrosis Foundation

Tim Clontz
Senior Vice President for Health Services
Cone Health

Richard A. Courtney
Elder Law Attorney and President
The Special Needs Alliance

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[28] Congressional Budget Office, *Cost Estimate: S. 349 Special Needs Trust Fairness Act of 2015* (July 10, 2015) (online at https://www.cbo.gov/sites/default/files/114th-congress-2015-2016/costestimate/s3491.pdf).