



805 15TH STREET NW • SUITE 615 • WASHINGTON, D.C. 20005

February 25, 2015

VIA EMAIL

The Honorable Fred Upton
Chairman, Committee on Energy & Commerce
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

Re: 21st Century Cures Act – Comments on Draft Legislation

Dear Chairman Upton:

The Senior Care Pharmacy Coalition (SCPC) appreciates the opportunity to provide comments on the discussion draft of the “21st Century Cures Act.” We represent companies that own and operate independent long-term care (LTC) pharmacies in roughly 40 states, which serve over 325,000 residents in skilled nursing facilities (SNFs) and assisted living facilities (ALFs). Our members have combined annual revenues of more than \$1.7 billion.

We support the Committee’s goal of improving the Medicare prescription drug program through the prevention of fraud and abuse. We are concerned, however, that certain provisions of the draft—in particular, the Prescription Drug Plan (PDP) Drug Safety Program established in section 4281 and the definition of “credible allegation of fraud” in section 4282—fail to consider the very specific role that LTC pharmacies play in serving Part D beneficiaries in SNFs and ALFs, the heightened regulatory scrutiny LTC pharmacies already face under Part D, and the very low probability that LTC facility patients will have any realistic opportunity to abuse prescription medications. We therefore urge the Committee to reconsider how these provisions apply, and if they should apply, to Part D beneficiaries residing in SNFs and ALFs.

LTC Pharmacy Background

LTC pharmacies, sometimes called “closed door” or “institutional” pharmacies, are a distinct subset within the pharmacy community. Each SNF and many ALFs contract with a single LTC pharmacy to provide not only prescription medications, but also an array of consulting pharmacy and care planning services required by Medicare and Medicaid, state licensure laws, and professional standards.¹ The requirements imposed on LTC pharmacies

¹ Medicare Part D imposes significant requirements on LTC pharmacies that go well beyond those imposed on retail pharmacies. Medicare Conditions of Participation impose separate obligations on SNFs to contract with a LTC pharmacy that must provide substantial patient oversight, care management and medication management. These responsibilities devolve to LTC pharmacies by contract with SNFs. In ALFs, the provider-based requirements vary based on state law. While ALFs typically contract with a LTC pharmacy

are significantly more stringent than those imposed on retail pharmacies, including intensive pharmacist involvement in medication and patient care management.

The consultative, advisory, and care management services LTC pharmacies provide are crucial to continuity of care, as well as to the quality of care that patients receive. The average LTC facility resident takes 11 to 13 prescription medications each day. Medications for residents change frequently, particularly within 30 days of admission to a facility and any time a resident undergoes a significant change in condition. In addition, particularly in SNFs, Part D beneficiaries in LTC settings have little or no opportunity to “pharmacy shop” or “physician shop” to facilitate drug abuse.

The way in which Medicare covers prescription medications often changes over the course of a patient’s stay in a SNF and, to a lesser extent, in an ALF. An increasing number of patients admitted to SNFs after a hospital stay transition from Part A coverage to Medicaid for direct LTC services (e.g., nursing care or assistance in activities of daily living), to Part B for certain types of covered services (e.g., physical therapy), and to Part D for pharmacy services. A similar dynamic arises when patients are admitted to SNFs or ALFs from the community. These types of care transitions not only raise coordination of care issues, but also how services are paid for depending on the location from which and to which a patient moves. Given the complex reimbursement scenarios applicable to patients in SNFs, any global Part D changes must be considered very carefully in the LTC context to prevent unintended and adverse consequences for Medicare beneficiaries.

PDP Safety Program

The PDP Drug Safety Program established in section 4281 of the Committee’s draft should be modified to accommodate the specialized capacity of LTC pharmacies to avoid abuse of controlled substances while serving the needs of SNF and ALF residents. LTC pharmacies already provide greater oversight of prescription dispensing and usage than the provisions of section 4281 require. In addition, due to substantial differences between retail and LTC pharmacies, the provision as drafted would pose significant quality of care and compliance issues for LTC facilities and would undermine Medicare beneficiary choice in selecting LTC facilities.

The SCPC is concerned that this “safe pharmacy network” provision does not recognize the practical and operational realities of providing Part D medications and related services to beneficiaries in SNFs and ALFs. As noted above, each SNF and many ALFs typically contract with a single LTC pharmacy to assure consistency in packaging, common oversight, and improved patient safety. Those LTC pharmacies must comply with myriad requirements that do not apply to retail pharmacies. As a result, retail pharmacies may not be legally able to provide medications to Medicare Part D beneficiaries (or any other patients) in LTC facilities, particularly in SNFs.

to serve its residents, the degree to which more than one pharmacy serves ALF patients varies more widely than in SNFs, due to different state law requirements and the health care needs of ALF residents.

The SCPC is particularly concerned that PDPs are not required to include LTC pharmacies in their “safe pharmacy networks,” nor are they required to ensure that all SNFs that are participating Medicare providers in the PDP’s market contract with LTC pharmacies that also are in the PDP’s safe pharmacy network. If no LTC pharmacy contracting with a particular SNF or ALF is part of the relevant PDP’s safe pharmacy network, a Part D beneficiary in a particular LTC facility may not be able to obtain needed medications because no pharmacy in the safe pharmacy network legally would be able to provide medications to patients in that facility. This would subject Part D beneficiaries to serious complications and an increased likelihood of hospital readmissions.

The SCPC is also concerned that the provision could limit patient choice improperly. Patients choose a SNF or ALF for many reasons. However, it is their choice, not the choice of a PDP, and it is never based upon whether a particular LTC pharmacy contracts with a particular SNF or ALF. Under the draft legislation, once a PDP chooses the members of its safe pharmacy network, it essentially dictates the beneficiary’s choice of LTC facility if the beneficiary is required to participate in a safe pharmacy network.

Section 4281 fails to recognize that LTC pharmacies already are in a unique position to ensure the integrity of the Medicare Part D program. As the contracted pharmacy servicing a particular LTC facility, our members’ pharmacists already have oversight for the entire breadth of a patient’s drug regimen. The statutory and regulatory requirements Medicare imposes on LTC pharmacies, as well as the methods of packaging, dispensing and tracking medications and monitoring usage in LTC facilities, essentially mean that LTC pharmacies *are* safe pharmacies within the meaning of the draft legislation. These requirements include, but are not limited to: extensive pharmacy operations and prescription services, round-the-clock delivery, 24-hour on-call pharmacists, emergency medications, specialized packaging, comprehensive inventory, and the capacity to comply with all the reporting requirements necessary to provide those services. A comparison of these obligations with the safe pharmacy network requirements in section 4281 demonstrates that LTC pharmacies already provide greater oversight and protection than the requirements proposed for safe pharmacy networks.

The SCPC would welcome the opportunity to work with Committee staff to address these concerns. One potential solution might be to exempt either LTC pharmacies or Part D beneficiaries receiving care and services in LTC settings, and believe there are administratively simple ways to implement such a provision. Of course, we are open to alternative approaches and look forward to continuing dialogue on this issue.

Part D Suspension of Claims Payment

Section 4282 allows a PDP to suspend payments or notification of clean claims to a pharmacy pending an investigation of a “credible allegation of fraud.” While the SCPC supports the Committee’s objective of reducing fraud, we believe that this provision, particularly as applied in the context of LTC, raises serious concerns.

There are an estimated 900 to 1,200 LTC pharmacies across the country, most of which are very small. A lengthy suspension of Part D payments would be financially devastating to many of them. This is particularly unfair when the payment suspension is based entirely

on an allegation rather than a finding of fraud, and could be triggered by a single call to a Medicare hotline. Of particular concern, since SNFs contract predominantly with one LTC pharmacy, if that pharmacy were subject to suspension of payments by one or more PDPs, it likely would threaten the continuity of care and services provided to residents in those facilities.

In addition, LTC pharmacies enter into direct contracts with PDPs each year. These contracts typically include provisions negotiated between the pharmacies and the PDPs that govern the manner in which complaints of error or fraud will be adjudicated and resolved. These agreed-upon provisions achieve the same results sought by the draft legislation. Section 4282 would allow PDPs to override these contractual provisions based upon a “credible allegation of fraud.”

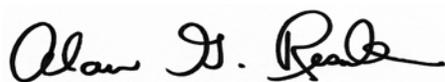
Finally, the draft affords LTC pharmacies no due process protections to prevent indefinite payment suspensions or provide rapid resolution of fraud allegations. The absence of reasonable provisions would threaten the very survival of the independent LTC pharmacies ensuring that Medicare beneficiaries and other residents of LTC facilities receive needed medications.

Medicare Part D operates most effectively when there is an appropriate marketplace balance in which PDPs, pharmaceutical manufacturers, wholesalers, and providers—including LTC pharmacies—work together to ensure that beneficiaries have timely access to the drugs they need. Policymakers must recognize that the program will work as intended only if the marketplace is balanced and if no participant gains too much control or leverage over the other participants. Imbalance already threatens the program vis-à-vis the relationship between PDPs and independent LTC pharmacies, and the SCPC is concerned that section 4282 vests too much authority, with too little statutory and regulatory guidance, in PDPs. Once again, the SCPC would welcome the opportunity to work with the Committee to craft a more balanced approach concerning independent LTC pharmacies and the Medicare beneficiaries in LTC facilities who rely on them.

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The SCPC appreciates your attention to these concerns. We look forward to working with you and other interested parties to address these issues in a way that reduces fraud and abuse in the Medicare program while recognizing the unique characteristics of LTC pharmacies and the specialized interests of the Medicare beneficiaries they serve.

Very truly yours,



Alan G. Rosenbloom
President and CEO

On behalf of the academic membership of the International Center for Regulatory Science, I would like to add our support for the proposed legislation to foster the nation's innovative capacity and to translate that capacity into economic and social good. The proposed bill recognizes explicitly what has been known for some time- that medical product development does not occur simply through the basic research that has been traditionally funded by granting agencies, but requires a concerted and integrated effort from cadres of skilled experts in the later development of those products, in fields as varied as formulation, design and process engineering, toxicology, quality and clinical affairs. These latter field are all part of an envelope of later-stage science known as "regulatory science". The definition of regulatory science varies, but that adopted by the Food and Drug Administration is...

*the **science** of developing new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of **FDA-regulated** products*

The proposed bill specifically addresses the issue of "helping emerging young scientists" in section 2261-2262. The future of our drug development enterprise is in their hands, but the system currently in place still plays by rules that seem outdated for the objectives addressed by this bill. It fails to acknowledge that a breadth of training is important from bed to beside. For example, students studying regulatory science are typically excluded from support through STEM programs. This problem is in part historic. When STEM disciplines were established so that students could be eligible for special scholarships, programs and governmental support, the notion was that basic science and engineering were the disciplines on which emphasis should be placed. Programs to educate strong science students in later stage disciplines did not really exist at that time. However, in the last 15 years, driven by a shortage of trained regulatory scientists, a number of regulatory science programs developed and Centers for Excellence in Regulatory Science emerged. It is ironic that students in such programs are not typically included under the STEM umbrella. Without such a designation, students lose access to the opportunities normally given to graduate students in science and engineering. Many students thus may see the pursuit of science training in translational, clinical or regulatory areas as less appreciated, and instead pursue graduate degrees in basic science, where there is currently an overabundance of training given the job needs for such skills.

If legislation is intended to assure a strong future generation of regulatory and translational scientists, it is important to examine all of the impediments, so that the good objectives of the proposed legislation are not subverted by systemic, exclusionary educational boundaries. The bill provides the opportunity to instruct appropriate agencies to reevaluate the inclusion of graduate programs in regulatory, quality and clinical science as disciplines included under the STEM designation. Such a step would essentially cost nothing but would go a long way toward legitimizing the study of much needed translational disciplines that recent surveys have shown to be in particularly short supply (https://regulatory.usc.edu/files/2014/08/Locke_Richmond_Hiring_training_needs_Aug_2014.pdf). It would send a signal that science of all types are important, and that training students in the emerging fields of regulatory science and product development are legitimate academic activities.

Thank you for the opportunity to raise awareness about this specific issue, in the context of improving our national capacity in drug development.

Sincerely

Frances Richmond

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February 24, 2014

The Honorable Fred Upton
Chairman
Energy & Commerce Committee
United States House of Representatives
Washington, DC 20515

The Honorable Frank Pallone, Jr.
Ranking Member
Energy & Commerce Committee
United States House of Representatives
Washington, DC 20515

Dear Chairman Upton and Ranking Member Pallone:

The Visiting Nurse Associations of America (VNAA) applauds the development of the 21st Century Cures draft legislation and thanks you for the opportunity to comment. We support the goals of this legislation and encourage the development of innovative and life-saving health care and research, while protecting consumer choice and access to high quality care.

VNAA's nonprofit home health and hospice members have a proven track record of furnishing high quality, patient-centered care at home as well as supporting family caregivers who assist homebound patients. Home-based care ranges from preventive and public health services to comprehensive advanced illness management that provides clinical care in combination with emotional and spiritual support. Nonprofit home health agencies, by mission and design, serve all beneficiaries regardless of their ability to pay. In many cases, Medicare beneficiaries who receive home health care are older, sicker and poorer than the overall Medicare population. This includes vulnerable beneficiaries and beneficiaries with multiple chronic conditions.

VNAA members fill a unique roll in the delivery system and in the community as they serve every beneficiary without regards to their ability to pay. The typical case mix of a nonprofit home health or hospice agency includes many vulnerable patients and those with multiple chronic conditions. Changes to payment policy dramatically and disproportionately impact these agencies. As policymakers consider how to innovate the health care delivery system and fill in the gaps on cures, we encourage them to ensure that patients, including those who qualify for the Medicare home health benefit, should have access to a wide choice of qualified providers and treatments to serve their unique needs; and that reimbursement be sufficient to ensure access for all beneficiaries to high quality providers.

In order to ensure that patients have a choice of high quality providers—and access to these providers—VNAA is interested in the results of the provider consolidation studies proposed in this draft legislation. We encourage a focus on the impact on beneficiary access to a wide range of providers as a result of provider consolidation, with a special focus on the needs of low-income beneficiaries.

VNAA strongly supports the Committee's interest to pursue the expansion of telehealth services in Medicare. Telehealth can play an important role in supporting the delivery of needed health care

services in the home while also improving patient care and reducing costs. Our members already widely—and at their own expense—use remote patient monitoring and telehealth services to provide better and more efficient care to patients. VNAA strongly supports granting the Secretary discretion to waive any limitations within 1834(m) of the Social Security Act relating to what qualifies as an originating site. We urge the Committee to designate the patient’s home as an originating site in statute.

VNAA deeply appreciates the opportunity to provide feedback and input in the development of this important legislation. We look forward to working with you and your staff to advance this initiative.

Sincerely,

A handwritten signature in blue ink, reading "Tracey Moorhead". The signature is fluid and cursive, with the first name "Tracey" and last name "Moorhead" clearly legible.

Tracey Moorhead
President and CEO



February 23, 2015

The Honorable Fred Upton
Chairman
House Committee on Energy & Commerce
2125 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Upton:

On behalf of VIVUS Inc. (VIVUS), I am pleased to have this opportunity to submit comments on your 21st Century Cures discussion draft, which was released on January 27, 2015. VIVUS is a biopharmaceutical company developing innovative, next-generation therapies to address unmet needs in areas such as obesity, diabetes, and sleep apnea. We applaud your efforts in this discussion draft and for accepting comments that would enhance the regulatory framework in support of biomedical innovation in the United States.

Innovative medicines contribute enormous health, economic, and social welfare benefits to individuals. A healthy population is also more productive and less costly to public health programs. At VIVUS, we developed the weight management medication, Qsymia[®] (phentermine and topiramate extended-release) capsules CIV. Qsymia was approved by the Food and Drug Administration (FDA) in 2012 and is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adult patients with an initial BMI of 30 or greater (obese), or 27 or greater (overweight) in the presence of at least one weight-related comorbidity such as hypertension, type 2 diabetes, or dyslipidemia.

Obesity is a major public health issue in our country. Around 36 percent of adults in the United States are obese, while many others are overweight and may soon be contending with obesity. Unfortunately, anyone who is overweight or obese can face health consequences. Obesity is linked to heart disease, stroke, cancer, type 2 diabetes, dyslipidemia, joint issues, obstructive sleep apnea, and many other conditions. Beyond the health risks, obesity carries significant stigma. Weight prejudice can have profound consequences in social acceptance, employment and even medical care. Tragically, these societal biases ignore an important fact: obesity is a medical condition as declared by the American Medical Association in 2013.

Given obesity's many consequences, people have a strong incentive to lose weight. While diet and exercise may succeed in the short-term, many have trouble maintaining their weight loss. The inability to maintain weight loss is not a function of will, but rather of biology. Obesity restructures how the body responds to food, and thus, measures beyond basic diet and exercise are sometimes required. Bariatric surgery has helped many people achieve significant weight

loss. More recently, pharmaceutical companies have developed a new generation of weight loss drugs. There are currently four FDA-approved medications for chronic weight management and more are in the pipeline.

Even with these advances, barriers to these medications for patients remain. Though many private health insurance policies cover anti-obesity and weight management drugs, Medicare does not cover them under Part D as there were no FDA-approved weight management drugs at the time the Part D program was created. The Social Security Act (specifically Section of Title 19), which, governs the Medicare Part D program, excludes or restricts certain drugs from basic coverage. Specifically, “agents when used for anorexia, weight loss, or weight gain,” are excluded from the definition of Part D covered drugs. Recently, Health and Human Services (HHS) Secretary Burwell has stated that expansion of Part D coverage would require a legislative change by Congress and has offered HHS staff to provide technical assistance while drafting such language. While coverage under Part D is not allowed, Part D plans wishing to provide coverage of chronic weight management medications may do so as a supplemental benefit as they can with other drugs that are excluded from the definition of Part D drugs.

Typically, payers and employers design drug benefit plans based on Part D guidance/requirements. Exclusion of anti-obesity and weight-management drugs from Part D creates further barriers for employers to add these therapies into their standard benefit design. Employers who want to cover anti-obesity and weight-management drugs need to buy a separate rider which is a cumbersome process creating more hurdles for patients to access these important therapies.

Along with many private health insurers, Federal government departments and agencies have recognized the adverse and costly impact of obesity and related chronic conditions to their beneficiaries and increasingly provided coverage for FDA-approved prescription drugs for obesity and weight management. In early 2014, the Office of Personnel Management announced that all insurance carriers offering coverage under the Federal Employees Health Benefits (FEHB) Program should cover prescription medications approved by the FDA for obesity. Shortly thereafter, the Department of Veterans Affairs and the Department of Defense released practice guidelines for obesity treatment which include recommendations for obesity and weight management drugs.

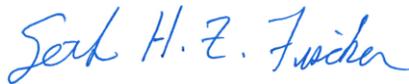
This disparity in coverage between Medicare and other payers puts Medicare beneficiaries at a great disadvantage. While they may be motivated to lose weight, they lack access to all available options. Between the human cost, the budgetary impact and the burden on our health care system, obesity has become an enormous policy issue. We must develop creative solutions to meet the policy challenge and allow our Medicare population to have the same access as individuals with private or other Federal coverage to help address obesity.

Last Congress, a former Energy & Commerce Member, Senator Bill Cassidy, introduced H.R. 2415, the Treat and Reduce Obesity Act. The bill would have authorized the Secretary to cover medications for the treatment of obesity or for weight loss management for an overweight individual with one or more comorbidities under Medicare Part D. The bi-partisan piece of legislation had 115 cosponsors in the House and over 40 patient groups, health care provider associations, and biomedical manufacturers supporting the measure.

It is clear that hard work has been put into the Committee's discussion draft and we agree with the goals that you have presented, especially: incorporating patient perspectives into the regulatory process; helping patients address their unmet medical needs; accelerating the discovery, development, and delivery cycle of medications; and supporting continued innovation at our Federal public health agencies. If the FDA approves medication to treat or cure a disease, all Americans should have access to it. Now we need to make sure that the Centers for Medicare and Medicaid Services has the legal authority to do so and request that you include such a provision in the Committee's bill.

We are pleased to see that so much work and dedication has gone into the 21st Century Cures initiative, and we are willing to make ourselves available as a resource to you and your staff at any time. We encourage the Committee to work with those who are battling obesity and overweight management issues, as it truly is a major health issue that needs to be addressed. Allowing every individual to have access to all the right tools will only help our country's health care system. If you have any questions or comments on this letter, please contact Sunil Karnawat at 510-566-7644 or karnawat@vivus.com.

Sincerely,

A handwritten signature in blue ink that reads "Seth H.Z. Fischer". The signature is written in a cursive, flowing style.

Seth H.Z. Fischer
Chief Executive Officer
VIVUS, Inc.