

Statement of
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Subcommittee on Health
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Chairman Burgess, Ranking Member Green and members of the Subcommittee, thank you for the opportunity to speak to you regarding the importance of the 340B Program. I commend your leadership in ensuring the integrity of the program and hope to give your subcommittee meaningful feedback on policy related to the program.

My name is Fred Cerise and for the last four years I have served as the President and CEO of Parkland Health & Hospital System. I am a member of the Medicaid and CHIP Payment and Access Commission, the chair of the Teaching Hospitals of Texas and sit on the board of the Texas Hospital Association. I am appearing here today on behalf of Parkland Health & Hospital System; my testimony reflects my views as the CEO of Parkland.

Located in Dallas County, Texas, Parkland is one of the largest safety-net health systems in the country. The system includes an 878 bed acute care hospital, twelve primary care clinics, twelve youth and family centers, ten women's health clinics, acute response clinics, homeless outreach, jail health and nursing homes. We are the primary teaching hospital for the University of Texas Southwestern Medical Center and recognized nationally for our Level I Trauma, Level III NNICU and one of the largest civilian burn units in the nation. We are also proud to claim Chairman Burgess as one of the many excellent physicians who have trained at

our facility. We appreciate his continuing support of Parkland and his understanding of our mission.

In fiscal year 2017, Parkland provided approximately \$879 million in uncompensated care. Our payor mix for that year was 45% uninsured, 31% Medicaid, 16% Medicare and 8% commercial insurance. We provided more than 1.2 million outpatient visits and filled over 10.5 million prescriptions in both outpatient and inpatient settings. Our pharmacy's payor mix was over 62% charity care. Parkland's pharmacy department includes one inpatient, seven retail, one central fill and 26 Class D clinic pharmacies.

Overview of Parkland's 340B Program

Parkland has participated in the 340B Program since its inception. The program is a critical component to fulfilling our mission to serve the most vulnerable in our communities. Our Medicare DSH percentage for fiscal year 2017 was 47.52% well above the 340B eligibility threshold of 11.75%. The health system holds 101 HRSA site registrations: one parent (DSH), 83 child sites (DSH), ten family planning sites and seven FQHC sites.

In 2017, the 340B Program saved Parkland and the Dallas County taxpayers who support us \$152 million. Still, 9% of Parkland's budget was spent on pharmaceuticals. The cost of pharmaceuticals to Parkland has more than doubled in the last ten years and the cost of prescription drugs is often a barrier to receiving appropriate healthcare for working low-income residents. The 340B savings allow the health system to administer free and reduced-cost medicines, often at a lower cost than 340B prices, to low-income patients, which is a benefit to both those patients and the taxpayers.

Under our Parkland Financial Assistance program, Dallas County residents who are under 100% of poverty receive drugs at no cost. Dallas County residents between 101% of the Federal Poverty Income Level and 250% of the FPIL receive significantly discounted drugs based on a sliding scale between \$5 and \$15. That represents the total cost to the patient regardless of our acquisition costs. Additional programs supported by 340B savings include: expansions in access to care including homeless outreach, diabetes management, pediatric asthma programs and smoking cessation education. Parkland also recently embarked on a sophisticated medication adherence program. Our healthcare providers now are able to see in a patient's electronic medical record whether that patient has filled their prescriptions and thus their level of adherence to prescribed medications. For this tool we compile pharmacy fill data from Parkland pharmacies and pharmacies outside our system. This adherence data better guides patient conversations. Instead of guessing why someone's diabetes is poorly controlled providers use this adherence score to quickly rule in or rule out medication nonadherence. The provider may then start a conversation with, "I see that you might be having some trouble filling your medications, can you tell me more about that?" Providers can better tailor medical treatments for chronic diseases with accurate information and can all upon our pharmacists and care managers to help patients overcome any barriers to obtaining their needed medications.

Parkland's Compliance and Oversight of 340B

Compliance is an incredibly important and essential piece of the program. We have one dedicated 340B manager assigned to oversee the program and he serves as the primary contact

for HRSA. We also established a multi-disciplinary team to assist with compliance which includes staff from pharmacy, legal, corporate compliance, government reimbursement, procurement and information technology. We believe self-audits are the backbone of a compliant 340B Program. We perform quarterly scheduled audits on both the inpatient and outpatient areas. We also perform other targeted audits throughout the year in order to better ensure program compliance. Our audits are based on educational materials and guidance provided by the Prime Vendor Program, Apexus. While we believe we are thorough in self-auditing, clearer guidance by HRSA would strengthen compliance adherence by covered entities.

Contract Pharmacy

Parkland does not currently have any contract pharmacy relationships. We have had companies solicit Parkland to develop a contract pharmacy relationship in order to generate savings. We are fortunate to be able to provide all of our 340B pharmacy services in-house. While contract pharmacy savings could be used to further care for our low-income patients, we share Congress' concern that some pharmacies may prioritize revenue generation over providing the lowest cost prescriptions to the consumer.

RECOMMENDATIONS

- 1) **Program Intent:** The original intent of the 340B Program was to “enable covered entities to stretch scarce Federal resources as far as possible.” This intent is still relevant today and therefore we believe Congress should not modify the intent to narrow the eligibility of the patient or limit the uses of the savings. 340B savings are used to provide free and

reduced cost drugs. Savings are also used system-wide to benefit our patients, the majority of whom are uninsured or on Medicaid. In 2017, Parkland dispensed 1.6 million outpatient prescriptions. Tracking each of these prescriptions by site of origin or by individual patient characteristics would be very difficult to manage. All Parkland outpatient clinics are registered with HRSA and our pharmacies only fill 340B eligible prescriptions. Therefore, we only maintain a 340B drug inventory at each pharmacy. Even though an overwhelming majority of our patients are indigent, narrowing the program's scope to a certain patient qualifier (regardless of the number qualified – 1% or 99% of patients), would require the use of a wholesale acquisition cost (WAC) based virtual inventory. Limiting 340B drugs to certain patient types would require the purchase of more expensive pharmaceuticals for our other patients, more tracking software and more human resources to operate and maintain compliance.

- 2) **HRSA Oversight:** Parkland supports efforts to strengthen HRSA oversight to police both covered entities and drug manufacturers. The agency must be given the appropriate tools to ensure the integrity of the program. Covered entities must be given clear regulatory guidance.
- 3) **Reporting of Savings and Uses:** Covered entities should be transparent in how the 340B Program is being used to provide charity care to patients and we support reporting the savings to HRSA. Any reporting requirements should clearly define the method of how to calculate the savings. Congress and HRSA should continue to allow flexibility on how covered entities use the savings. Preventive care is essential to maintaining good health, lowering healthcare costs and having a better quality of life. While drug costs are a

critical piece of the puzzle, providing other medical services may be just as important. Therefore, we believe savings should be allowed to be used for more than just lowering drug costs for the indigent population.

- 4) Restore Medicare Outpatient Prospective Payment Cuts:** The cuts significantly harm safety-net systems, which are providing the majority of care to those who are low-income and uninsured. The increased burden for Dallas County taxpayers for the top 21 drugs is \$2.2 million. Health systems with a larger Medicare population are seeing larger decreases in payments. Additionally, the modifier reporting regulations are burdensome by requiring complex programming with quarterly updates to place specific modifiers on select drugs.
- 5) Contract Pharmacies:** These pharmacies are essential for many 340B participants to extend access to low-cost drugs for many patients since not all entities are able to have in-house pharmacies. Better oversight is needed to ensure that these arrangements are appropriately targeting low-income patients and that these patients are benefitting from the 340B prices.
- 6) Moratorium on new 340B entities and child-sites:** A moratorium will only limit access for persons who are low-income. As the population grows and demographics change, safety-net systems should be allowed to receive 340B discounts via new clinics or new accounting cost centers in order to serve the indigent according to the intent of the program. If this moratorium is being used to limit the number of new covered entities or child sites, do not limit those providers who are truly caring for the low-income and uninsured. Many of those safety-net systems like Parkland serve patients in medically-

underserved areas and make decisions on clinic locations based on the needs of their communities. If the intent is to limit the scope of the program a preferred approach would be to increase the DSH percentage.