Parkland

The Honorable Michael Burgess, MD
Chairman
Energy and Commerce Subcommittee on Health
2125 Rayburn House Office Building
Washington, DC 20515

August 15, 2018

Dear Chairman Burgess, Ranking Member Green and members of the subcommittee:
Thank you for the opportunity to share additional information about Parkland Health & Hospital System's 340B program. I was honored to speak at your hearing last month and I hope these answers to your questions provide further insight to the importance of this program to Parkland's patients.

The Honorable Michael C. Burgess, MD

1. One thing that has been consistently reported by the GAO, HHS OIG, as well as published studies in JAMA (Journal of the American Medical Association) and Health Affairs, is the lack of transparency in the 340B program. Increased reporting, of the right measures, would allow Congress to understand how the 340B program dollars are being used to meet the health care needs of vulnerable patients. I find it interesting that some, but not all, 340B hospitals continue to say that on the one hand "they already have extensive reporting" but on the other hand "adding reporting would be onerous". This is circular logic. Hospitals do have the infrastructure to report measures – as they have emphasized that they currently have extensive reporting--- but some seem less interested in working with Congress to make sure that the measures reported on help improve the program. I think that we have lost sight of the fact that this program is completely VOLUNTARY. No one is forcing any entity to participate, and those who do not want to improve transparency can also choose to not participate in the program. Why do you think that some hospitals continue to say they cannot report measures?

Hospitals like Parkland are more than willing to report our savings data and how we use the savings to meet the healthcare needs of our patients. Perhaps some of the smaller or rural hospitals do not have as sophisticated IT systems and dedicated staff required to collect the specific details to the individual patient level and therefore it makes reporting more manually and administratively burdensome. Hospitals participating in the program should be able to report minimum requirements such as drug costs avoided as a result of the 340B program, programs/services that the 340B savings funds and the number of uncompensated care patients served. Drug savings reporting measures by child site is more difficult to accomplish because not all prescriptions are submitted electronically by physicians, therefore a manual process to trace the location of the site has to be developed.

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2. Currently, certain rural and cancer hospitals are unable to access 340B pricing for orphan drugs, even when they are not being used to treat rare conditions. H.R. 2889, the "Closing Loopholes for Orphan Drugs Act" amends the Public Health Service Act to revise the 340B Drug Pricing Program to discount orphan drugs that are not being used to treat rare conditions for all entities covered by the program.

   a. Can Parkland Hospital acquire orphan drugs at 340B discounted prices when they use these drugs for non-orphan diseases or conditions?

      i. If so, how does acquiring these drugs at 340B discounted prices help Parkland Hospital serve vulnerable and low-income patients?

2a. Yes, Parkland can purchase orphan drugs for non-orphan diseases or conditions at 340B prices.
2a.i. The majority of our patients are low income and are able to get their prescription drugs at a very low or no copay. Our uncompensated care last year far exceeded our 340B drug savings. Any dollar saved goes toward efforts such as purchasing new expensive chemotherapy for patients without the ability to pay for treatment, unique patient care programs/services or to support Parkland's nominal drug copays.

   b. Do you think it makes sense that some 340B covered entities can access 340B pricing for orphan drugs that are not being used to treat rare conditions while other 340B covered entities cannot buy these medicines at 340B prices?

No it does not make sense and limits access. If a 340B price is available, it seems logical to think it should be available to everyone participating in the 340B program. However, there are other differences in the 340B entity landscape as well. For example, some entities have to abide by the GPO prohibition whereas others do not.

3. There are concerns that some drug manufacturers have claimed orphan status for a drug and then marketed it for more common conditions without having to provide a 340B discount to some covered entities even when the drug is used for these more common conditions. If this is indeed happening, do you think H.R. 2889 would limit manipulation of the orphan drug exclusion?

Yes we believe H.R. 2889 would limit manufacturer manipulation of orphan drug use.

The Honorable Robert E. Latta

1. How do you know that your 340B savings are benefitting low income and uninsured patients, and what do you do to ensure that these patients can afford their prescriptions?

Parkland Health & Hospital System is the public hospital for Dallas County, Texas. In 2017, our payor mix was over 75 percent uninsured or on Medicaid. 340B savings directly benefit low-income patients because we have a charity care program that provides financial assistance for medical care for Dallas County residents who are at 250 percent or below the Federal Poverty Income Level (FPIL). As part of

our Parkland Financial Assistance (PFA) program, we provide drugs at significantly reduced cost or at no cost to these patients. Applicants for the PFA program undergo a financial screening to determine potential funding sources and his or her ability to pay. The extent to which a resident will be financially responsible will be determined based upon pre-established financial criteria. Patients enrolled in PFA and who are under 100 percent of FPIL receive prescriptions at no cost at Parkland pharmacies. Patients who are enrolled in PFA and between 101 percent - 250 percent of FPIL are charged between $5 - $15 per prescription. These charges may potentially be reduced or waived if the patient is unable to pay.

Our uncompensated care last year far exceeded our 340B drug savings. Any dollar amount saved on pharmaceuticals goes toward the effort of providing patient care programs/services, supporting our nominal prescription copay program, and providing clinic administered medications for patients who are low-income. Medications used may range in cost from a few dollars to many thousands of dollars for expensive life-saving chemotherapy agents that are frequently given in the outpatient setting.

The Honorable Leonard Lance

1. How do you believe HRSA could more efficiently administer and oversee this program?

The ability to have rulemaking authority can increase efficiency, but there should be ample opportunities for stakeholder input for any regulation changes. HRSA needs an adequate number of staff to oversee the program. Additionally, HRSA should have the ability to provide real-time guidance and clarification of rules as needed either through modification of requirements or improving access to staff (i.e. HRSA or Apexus) with authority to provide clarity. An efficiency enhancement might also include increased capabilities for the OPA information system (OPAIS) including the ability to change basic information (phone numbers, shipping addresses, authorizing official and primary contact) for multiple sites at one time. The current method requires HRSA approval for any changes at each 340B site to be done separately. We also believe allowing new registrations to occur more frequently can enhance program administration efficiency. Additionally, we would like the ability for covered entities to receive 340B discounts for new child sites without waiting a year for a cost report.

2. What actions do you take to ensure compliance with existing regulations and guidelines set forth by HRSA?

We make a concerted effort to be aware of 340B program regulations and guidelines and utilize the Prime Vendor Program, Apexus, for information. We have hired a manager who dedicates his time to oversee the operations of the 340B program at Parkland, serve as the primary contact for HRSA, and serves as the subject matter expert on 340B for Parkland. We also have a multi-disciplinary team that has a standing monthly meeting to assist with program compliance oversight and includes staff from pharmacy, legal, corporate compliance, government reimbursement, procurement and information technology. We have developed internal audits based on educational materials and guidance provided by Apexus. These internal audits are performed on a quarterly basis. We also perform other targeted audits throughout the year in order to better ensure program integrity. With these audits, we evaluate

program requirements including: patient, provider and location eligibility, Medicaid duplicate discount prevention, proper drug accumulation and purchasing records.

The Honorable H. Morgan Griffith

1. Since entering the 340B program, has your hospital acquired "child sites", and if so, what is the reasoning behind these purchases? What types of practices has your hospital-acquired?

While Parkland has 83 child sites, none of them were purchased or acquired from a previous owner. The child sites were established by Parkland and are all owned and operated by Parkland to improve access to medical care for underserved patients in Dallas County.

The Honorable Gus M. Bilirakis

1. My colleague Dr. Burgess has a discussion draft that would amend the Public Health Service Act to require the Secretary of Health and Human Services to conduct audits under the 340B drug discount program in accordance with generally accepted government auditing standards. I think this is a good idea and one that would help improve the audits HRSA performs moving forward.

a. Is there evidence that indicates HRSA's audits have increased the integrity of the 340B program?

Yes, we believe HRSA's audits have increased the integrity of the program. Previously, we were provided outside legal guidance, which was deemed to be incorrect during a HRSA audit. As a result of this audit we have changed our practice to improve compliance and have strengthened our internal auditing.

b. How do you think HRSA could best assess noncompliance? How could they ensure compliance before closing an audit?

HRSA could require specific metrics for 340B entities to track and require that we provide feedback to HRSA in a timely manner. Additionally, if an area of noncompliance was found at a 340B site during an initial audit, HRSA could require corrective action and a re-audit after an action plan has been implemented.

c. Because HRSA's audits only review a small number of drugs purchased through the 340B program, is it possible that instances of noncompliance could be much larger than audits suggest?

It is possible. Noncompliance due to incorrect system processes could be larger than the audit suggests whereas isolated errors would be in line with initial findings.

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The Honorable Billy Long

1. In instances where a covered entity passes on the 340B discount to the patient in an in-house pharmacy, why would they not provide that same discount at one of their contract pharmacies?

Contract pharmacy agreement terms are negotiated by both parties and usually involve the contract pharmacy receiving a percentage of 340B savings, a flat fee or both. Passing on the full or majority of the drug savings could cause the entity to lose money by paying more in contract pharmacy fees than it saved with 340B drugs.
We agree that 340B savings achieved through contract pharmacies should be passed back to the patient after the covered entity recovers its reasonable costs.

2. In what ways do you benefit from contract pharmacy arrangements, and how do they help you achieve your mission?

We currently do not have any contract pharmacy relationships. We are fortunate to have multiple entity-owned retail pharmacies geographically located in the community we serve.

3. Finally, do you think HRSA should issue guidance on how to determine patient eligibility for drug discounts?

Guidance should be issued pertaining to covered entity eligibility (DSH percentage or another determined metric). Determining eligibility on a per patient basis would be burdensome and more expensive for Parkland. While a majority of our patients would meet indigent or charity care criteria, changing to a per-patient eligibility criteria would require significant modifications to our operations. We currently only utilize 340B inventory for the majority of our sites; changing requirements would necessitate switching to a more expensive (WAC priced) drug inventory, purchasing additional 340B tracking software, and require more labor for auditing to ensure compliance.

The Honorable Larry Bucshon

1. How do you calculate your 340B savings, and do you set aside these savings for specific programs and initiatives, or do they go into a general fund?

We sum all drug savings generated and then subtract any additional drug expense incurred due to the GPO Prohibition (i.e., WAC expenditures). The savings go into a general fund to support our organizational mission.
Here is our formula:

(GPO – 340B) – (WAC – GPO)

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Savings - Extra expense

(GPO – 340B) for 340B purchases: Difference between GPO cost (or next best available pricing w/o the 340B program) and 340B cost

(WAC – GPO) for WAC purchases: Difference between WAC cost and GPO cost (or next best available pricing w/o the 340B program)

2. Are covered entities required to report their savings to HRSA, and if not, does HRSA keep track of 340B savings through some other mechanism?

No, reporting savings is not currently required by HRSA. We are not aware of HRSA tracking this through other mechanisms.

3. Is HRSA tracking how 340B revenue is spent?

We are not aware.

4. Is there evidence that indicates covered entities are using 340B revenue for the original intended purposes of the program?

There is no formal reporting process to ensure hospitals are using the 340B savings for the original intended purpose. We can validate through our own system reporting that we are using 340B savings/revenue according to its intent. We would also welcome transparency requirements for standardized reporting.

5. How do you know that your 340B savings are benefitting low income and uninsured patients, and what do you do to ensure that these patients can afford their prescriptions?

Parkland Health & Hospital System is the public hospital for Dallas County, Texas. In 2017, our payor mix was over 75 percent uninsured or on Medicaid. 340B savings directly benefit low-income patients because we have a robust charity care program that provides financial assistance for medical care for Dallas County residents who are at 250 percent of Federal Poverty Income Level (FPIL). As part of our Parkland Financial Assistance (PFA) program, we provide significantly reduced-cost drugs or drugs at no cost to these patients. Applicants for the PFA program undergo a financial screening to determine potential funding sources and his or her ability to pay. The extent to which a resident will be financially responsible will be determined based upon pre-established financial criteria. Patients enrolled in PFA and who are under 100 percent of FPIL receive prescriptions at no cost at Parkland pharmacies. Patients who are enrolled in PFA and between 101 percent - 250 percent of FPIL are charged between $5 - $15 per prescription. These charges may potentially be reduced or waived if the patient is unable to pay.

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nominal prescription copay program, and providing clinic administered medications for patients who are low income. Medications used may range in cost from a few dollars to many thousands of dollars for expensive life-saving chemotherapy agents that are frequently given in the outpatient setting.

6. Would you support legislation to track how 340B savings are spent, and do you have any ideas or recommendations on how that would work?

Yes, we would support legislation that would track how 340B savings are spent. We recommend requiring a reporting mechanism that shows spending on behalf of the uninsured and underinsured population that goes beyond bad debt calculation using billed charges as the amount of charity care administered and is separate from any spending claimed as "community benefit." This could take the form of reporting subsidies for drugs, support for outpatient services, or some other tangible program of care.

The Honorable Susan W. Brooks

1. Can you describe the types of comprehensive services that 340B covered entities provide that are not normally seen in non-340B hospitals?

340B covered entities, like Parkland, treat a disproportionate number of patients who are uninsured or on Medicaid. They are either public or private non-profit entities that often have a teaching mission. These safety-net systems often have a network of outpatient clinics that provide comprehensive care. Parkland clinics, for instance, provide more than 1 million outpatient visits per year ranging from primary, preventive care (e.g., cancer screening, immunizations) to the management of complex chronic diseases. Nearly 50 percent of patients accessing these services are uninsured and their care is subsidized by Parkland.

2. In your opinion, what would be the best metric to determine an entity's commitment to serving low-income and uninsured individuals?

The best metric would be a measure that reports an entity's level of elective inpatient and comprehensive outpatient care for individuals who are low income and not just for outpatient care delivered in an emergency department. This comprehensive outpatient care metric should include outpatient clinic visits, Durable Medical Equipment provided, labs, radiology procedures, drug expenditure and physician costs for elective inpatient and outpatient care.

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The Honorable Markwayne Mullin

1. During a July 2017 hearing before the O&I subcommittee, HRSA testified that the Agency has struggled to clarify some of the 340B program requirements since they lack explicit regulatory authority for most provisions of the 340B statute and that "[s]pecific legislative authority to conduct rule making for all provisions in the 340B statute would be more effective for facilitating HRSA's oversight and management of the program. Specifically, regulatory authority would also allow HRSA to provide greater clarity and specificity of program requirements." Parkland Hospital uses the 340B program to serve a very high percentage of low income uninsured and Medicaid beneficiaries. Do you think that HRSA should have the authority to make sure that all covered entities are using the 340B program to help serve vulnerable and low-income patient populations?

Yes, HRSA should have the authority to ensure that all covered entities are using the 340B program to help serve vulnerable and low-income patient populations.

a. If so, do you think providing HRSA with the authority to prescribe regulations as necessary or appropriate to carry out the 340B program will help achieve this goal?

Yes, HRSA having the ability to provide program clarity would be beneficial.

The Honorable Richard Hudson

1. Does your entity provide 340B patients with drug discounts? How do you assess a patient's ability to pay for their prescriptions?

Yes, Parkland provides financial assistance for medical care for Dallas County residents who are at 250 percent of FPIL. As part of our Parkland Financial Assistance (PFA) program, we provide significantly reduced-cost drugs or drugs at no cost to these patients. Applicants for the PFA program undergo a financial screening to determine potential funding sources and his or her ability to pay. The extent to which a resident will be financially responsible will be determined based upon pre-established financial criteria. Patients enrolled in PFA and who are under 100 percent of FPIL receive prescriptions at no cost at Parkland pharmacies. Patients who are enrolled in PFA and between 101 percent - 250 percent of FPIL are charged between $5 - $15 per prescription. These charges may potentially be reduced or waived if the patient is unable to pay.

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2. What percentage of your patients receive free medicine from a patient assistance program that is offered by a biopharmaceutical company or other entity?

4.3 percent of our patients received free medicine from a manufacturer patient assistance program, our state's AIDS drug assistance program, or Texas' Vaccines for Children Program. The amount of free medicine from patient assistance programs offered by biopharmaceutical companies or other entities for 2017 was $63 million.

The Honorable Earl L. "Buddy" Carter

1. What level of charity care is your hospital providing, and how did you come up with that number?

Parkland spent more than $879 million in uncompensated care in 2017. This is the actual amount spent on care for patients for which Parkland was not reimbursed by the patient nor an insurer. Our charity care program provides financial assistance for medical care administered at Parkland for Dallas County residents who are under 250 percent FPIL. We also have established a self-pay charity care program with discounted rates for individuals who do not qualify for third-party insurance and are either above the 250 percent FPIL threshold or not a resident of Dallas County. We determined our charity care program benefit package based on a community needs assessment and available budget. You can access more information about our charity care program at: https://www.parklandhospital.com/phhs/parkland-financial-assistance.aspx.

2. Are child sites required to abide by the same HRSA obligations as the parent site?

Child site qualifying criteria (i.e., DSH percentage) falls under the umbrella of the parent site. Other regulations such as the Medicare Cost Report requirements, GPO prohibition, diversion, auditing, and Medicaid duplicate discount prevention are the same as the parent site.

The Honorable Frank Pallone, Jr.

1. The 340B program plays a critically important role in our health care system, and the countless hearings had in the Committee on this topic have reaffirmed that point on both sides of the aisle. However it is very important to make certain those dollars do, in fact, go towards expanding services as the statute dictates and that all covered entities are carrying out the 340B program with the people it is intended to serve at the center of any policy decision and in full and transparent compliance with the law.

    a. Dr. Cerise, can you explain the complexity of tracking savings from 340B discounted drugs? How does Parkland ensure these dollars go towards expanding services for vulnerable patients? Please provide the Committee with any relevant or illustrative documentation to that effect.

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Tracking 340B savings solely by comparing pricing is simple. However, it is important to note that "savings" do not always equal the same amount of money available to use elsewhere. If there is no insurance involved, then yes, what we saved is not complex to calculate. But when insurers like Medicaid, Medicare, and some private plans decrease reimbursement based on 340B enrollment, the revenue gain from purchasing a lower priced drug is negated. The percentage of the 340B payment reduction is likely greater than the percentage increase in spend to acquire the drug at a GPO price. In effect, there is "savings" on paper, but in reality, there is less money in hand.

We are able to calculate savings as a whole but calculating this for each child site can be complex. We have 83 medical care sites under our health-system, but only 7 retail pharmacies. We filled more than 1.6 million take-home prescriptions last year. Calculating savings for each site would require additional labor and assessment of successful computer programming to determine which prescription was written from each site. This would be burdensome and may not always be possible to do accurately since not all drugs are prescribed electronically.

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2. On June 1, HRSA issued a final rule delaying the implementation of the 340B Drug Pricing Program Ceiling Price and Civil Monetary Penalties regulation until July 1, 2019. In the final rule on the delay, HRSA notes that this delay will "allow a more deliberative process of considering alternative and supplemental regulatory provisions and to allow for sufficient time for any additional rulemaking…HHS intends to engage in additional or alternative rulemaking on these issues, and believes it would be counterproductive to effectuate the final rule prior to issuance of additional or alternative rulemaking on these issues."

    a. Can you describe and provide some information on the impact of this final rule to your institution? How would having access to ceiling prices change how the program is administered?

There is no major impact to Parkland related to the implementation delay of the Civil Monetary Penalties regulation. We believe both covered entities and manufacturers should be held to the same

standards. If there are questions or concerns about pricing, we will utilize our current channels (drug wholesaler, manufacturer and/or Apexus) for assistance.

Ceiling prices would be beneficial information to have for pricing validation. However, this would not really change the way we administer the 340B program at Parkland. We would still focus on complying with regulations and using 340B priced drugs to provide care our patient population.

3. As you know, the Medicare program has recently implemented a nearly 30 percent cut to 340B hospitals.

    a. Please describe the impact this change will have on your ability to care for patients.

The cost to Parkland is an estimated $2 million loss annually for the top 25 drugs. We have more demand for care than we can meet. Anything that lowers income or makes Medicare payments less predictable will inhibit our ability to plan for services to meet the needs of a large uninsured and low-income population.

Thank you again for the opportunity to provide you further guidance about the 340B program and its importance to our patients. Please do not hesitate to contact me should you have additional questions.

Sincerely,

Fred Cerise, MD
President and CEO
Parkland Health & Hospital System