TEXAS ONCOLOGY

August 14, 2018

Dr. Michael C Burgess
Chairman
Subcommittee on Health
Congress of the United States
House of Representatives
Committee on Energy and Commerce

Dear Chairman Burgess, Ranking Member Pallone, and esteemed representatives, thank you again for the opportunity to testify on opportunities to improve the 340B drug pricing program.

In response to your queries, please see the following included below. Please feel welcome to reach out with any additional questions.

The Honorable Michael C. Burgess, M.D.

1. I appreciate your testimony about the impact that the 340B program has on community oncology clinics. I want to point out that this same sentiment is shared by the US Oncology Network. The US Oncology Network believes that the 340B program growth is contributing to consolidation in oncology practices, thereby increasing monopoly power and prices to patients. In a recent resolution, the American Medical Association (AMA) pointed out that the 340B program does not support these physician practices. This could push consolidation beyond oncology to other areas where there is a clear financial incentive to capture revenue for specialties with high priced outpatient drugs. What can Congress do to combat the negative impacts of consolidation on this program while still ensuring that the program can be strengthened and maintained moving forward?

Thank you Chairman Burgess. Congress can take action to reform the 340B program. Legislation to heighten transparency, accountability, and clarify and clearly articulate the definition of a patient are among the most important steps Congress could take to improve the 340B program. Additional helpful steps would be increased resourcing and authority for oversight either through HRSA or another agency.
Transparency of program revenues, identification of qualifying patients, and clear vision on how these profits are used in the care of vulnerable patients would give the government more information on how 340B serves vulnerable patient populations. By requiring accountability to use 340B revenues in the care of vulnerable patients, these additional funds can be more precisely allocated to enhance the care of patient populations most in need. By clarifying the definition of a patient with 5 or 6 criteria, Congress can ensure that the 340b discount is being applied to patients managed by the hospital as opposed to generally applied to patients that may have touched the hospital at some point in their illness.

6204 Balcones Drive ♦ Austin, Texas 78731
Phone: (512) 427-9400 ♦ Fax: (512) 342-2723

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The Honorable Leonard Lance

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

HRSA is neither staffed appropriately to perform adequate audits nor are they empowered to act sufficiently when they see programs are in noncompliance. If I recall from prior HRSA testimony, I believe around 22 people at HRSA audit over 20,000 qualifying entities, and as a result only 1% of entities can be audited. HRSA needs to be resourced appropriately to perform meaningful audits. HRSA also needs to be granted the authority to enforce program compliance.

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?

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

1. **I don't know.**
2. **Yes. I think patient definition should be clarified and have enough criteria to suggest patients are active hospital patients, as opposed to a patient who has been cared for by the hospital at some point in the past.**

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The Honorable Larry Bucshon

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

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

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

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

1. **No. Many 340B qualifying entities may not quantify their own savings and there is no requirement to report those numbers to HRSA, but usually the vendors that track compliance for the 340B program that contract with hospitals to ensure compliance and perform analysis do estimate these numbers, but they also don't report them to HRSA.**
2. **No, presently there is no statutory mandate to report how incremental revenue is spent.**
3. **No, there is a complete lack of evidence because the program lacks statutory requirements for transparency. After speaking with 340B qualifying entities there appears to be great variability in the degree to which they pass on discounts, or use the program to provide services for vulnerable patient populations. That said, it is evident that some programs do use revenue to provide for at risk populations. Parkland Hospital is a great example of such a program. Their disproportionate and charity care provision is exceedingly high. However, clearly there are 340B qualifying entities that are not using the program revenue in alignment with original intent. When you see hospital systems with hundreds of millions of dollars in revenue from the 340B program and understand from local practices that unfunded patients are refused service while new lavish buildings are being built and executive compensation is high, it appears inconsistent with my understanding of the goals of the 340B program. We know that early entrants in to the program have a higher proportion of charity care in comparison to later entrants into the program from published data that I have included in this response.**[i]
4. **Yes. A good first step on collecting data is through the transparency requirements that are included in HR 4170. Right now it is impossible to track how hospitals specifically spend 340B revenue.**

The Honorable Susan W. Brooks

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

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1. **The best metric would be to quantify and report incremental revenue from the program and be transparent about how it is spent on vulnerable patient populations. Transparency has to be the necessary first step.**

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." Do you have any concerns with HRSA's oversight of the 340B program and/or 340B program integrity?

    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 alleviate some of these concerns?

1. **Yes. To your point, they are not staffed appropriately to conduct sufficient audits nor do they have the regulatory authority to conduct rule making for all provisions of the 340B program.**
    a. **Absolutely. I think this would greatly assist in 340B oversight and program integrity.**

The Honorable Frank Pallone, Jr.

1. Dr. Patt: You were asked the following question "Texas Oncology is a member of the US Oncology Network, which is a division of McKesson Corporation; is that correct?" You answered "No ma'am. Texas Oncology is a private practice." On the Texas Oncology website (https://www.texasoncology.com/who-we-are/affiliations/us-oncology-network), a page begins with the following sentence "Texas Oncology is member of The US Oncology Network."

    a. Please clarify your response for the record.

1. **Texas Oncology is not owned by The US Oncology Network or Mckesson Specialty Health. Texas Oncology is a private practice that provides multispecialty cancer care across the state of Texas and is comprised of physician partners, a managing board, and executive leadership. We are a member of The US Oncology Network which is a defined management services relationship with McKesson Specialty health facilitating implementation of electronic health record technology, research platforms, pharmacy and therapeutics, inventory management and many**

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other functionalities. It is not an ownership relationship. We are an independent practice owned by physician partners. My apologies if that was unclear in any way. When Representative Schakowsky from Illinois asked the question I thought she was implying that Texas Oncology is owned by McKesson Corporation, which it is not.

2. Dr. Patt: You stated that you work for a private practice in Texas. The bio you submitted to the committee states that you "led multiple innovative informatics and analytics initiatives within The US Oncology Network" and that you "serve[ ] as the medical director of analytics for McKesson Specialty Health" and "work[ ] with the McKesson team on a centralized 2021 analytics strategy."

    a. For purposes of clarification of your response, please provide the amount of annual compensation (of any kind) you receive from McKesson, if any, for your position with the company and the number of hours you spend on these activities for McKesson each month. Please provide information for the current year and the previous five year period.

2. In addition to my role in Texas Oncology, I am employed as a part time medical director for The US Oncology Network, McKesson Specialty Health as the medical director for analytics. The annual salary for this role is $30,000. I have held this role for roughly three years and the compensation has not changed. I would estimate I spend around 20 hours per month serving in this capacity.

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3. Dr. Patt: you have emphasized your "…collaborative relationship with Seton is extensive. For a decade, I ran their breast cancer services for the network. I chaired the breast cancer subcommittee, I still chair under the division of women's health, which is a collaboration between UT Dell Medical School and Seton…"

    a. Please clarify what Committee you chair and how it is affiliated with Seton or the University of Texas Medical School. Please also indicate how many people are on that committee, whether you hold meetings for this committee and, if so, whether you attend those meetings in person. Please provide a list of committee meeting dates and meeting attendees for the previous 12-month period.

3. I co-chair the access to care working group for Dell Medical School in the Livestrong Cancer Institute. It had its last official in person meeting in April of 2017 because Ascension Seton underwent organizational changes later that year, and the group's work to enhance access to care has shifted to other groups. As I recall, attendees at that meeting were Dr. Boone Goodgame with Ascension Seton, Dr. Philip Huang, Rebekkah Schear with Livestrong, Dr. Marian Williams-Brown the gynecologic oncologist that works with Seton in the outpatient clinic, Dr. Amy

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Young with UT Dell Medical School, Kate Henderson, CEO of Ascension Seton Main Hospital, Dr. Gail Eckhardt chair of Livestrong Cancer Institute, and Clarke Heidrick who co-chairs the committee. It is a collaborative committee between representatives from Seton, Dell Medical School, and community interests to assist in access to care issues for the underserved. Subsequent work on these issues has occurred in the Shivers Board who has been working with Dell Medical School. I serve on the Shivers board and over the last year we employed an individual to help characterize the burden of uninsured cancer patients in our community and formulate a plan of action, which we have presented to the medical school. We also have been working with Central Health, a healthcare organization that assists in providing care for patients in Travis county on the CCC that meets roughly quarterly on this issue and last met August 10, 2018. The CCC is a collaboration between Ascension Seton and Central Health. All of these meetings I have attended in person.

I am the breast health chair in the division of Women's health at Dell Medical School. We meet monthly at the Network Clinical Care Council (NC3) for Women's health. This is a collaborative committee between UT Dell Medical School and Ascension Seton where we discuss women's health related issues. My role in that meeting is to update the group on breast health issues like the underserved clinic and screening strategies. I attended by phone on Tuesday July 10, 2018 and to the best of my knowledge, Amy Brandes, Dr. Michael Nix, Dr. Karen Swenson, Dr. Molly Pont, Dr. Rebecca Rogers, Dr. Jacquie Bourdens, Dr. Elizabeth Polinard, Lisa Townsend, Amy Bullock, and Marnie Wheeler were present.

I chaired the breast subcommittee for the Ascension Seton Family of Hospitals from 2007-2018. Over the course of 10 years we developed breast specific tumor boards, designed and launched a breast center, and led quality improvement projects and addressed network breast health screening strategies. I also served as the medical director for the breast center, and helped fundraise for it's development. In the last year up until February of 2018, the multidisciplinary tumor board met every other week, and the subcommittee met every quarter. It was comprised of a representation of doctors and clinical staff including nurses, pathology, breast surgeons, plastic surgeons, radiation oncology, physical therapy and patient navigators.

4. Dr. Patt: In your testimony you state "[w]hen cancer care is shifted from private practices to the hospital outpatient department, the cost of care doubles."

    a. Please provide the Committee with specific data behind this statement.

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4. **As referenced in my testimony, Winn et al published in JAMA Oncology in April 2018 an article evaluating "Spending by commercial insurers on chemotherapy based on site of care, 2004-2014." This article uses the MarketScan database to evaluate commercial claims and encounters to estimate the cost for more than 280,000 patients with cancer who initiated treatment with infused chemotherapy and remained enrolled for 6 months and included sensitivity analysis for breast cancer patients to ensure consistent results. Adjusting for age, sex, year, and comorbidity as well as the fixed effects of reginal spending differences. Spending at the drug level was significantly lower in offices versus hospital outpatient departments ($1466 vs $3799 p<0.001). Day-level spending was lower for patients treated in offices compared to the hospital outpatient department ($3502 vs $7973 p<0.001). Total reimbursement during the six month treatment episode was also lower in offices in comparison to the hospital outpatient department ($43,700 vs $84,660p <0.001). Sensitivity analysis found consistent results. [ii]**
I submitted a copy of this paper with my written testimony and CV two days before the hearing and will submit it again with this response.
This kind of analysis is important because it illustrates the increased cost of consolidation of outpatient specialty cancer care in the hospital setting. When costs rise, it increases patients out of pocket costs and insurance premiums.

5. Dr. Patt: In your testimony you state "[w]hen 340B qualifying hospitals treat privately insured patients and prescribing these $10,000 drugs, each time they purchase the drug for $5,000 and keep nearly $5,000 in additional profits."

    a. Please provide the Committee with specific hospital financial data substantiating the statement that hospitals make a 100 percent profit off of drugs purchased under the 340B program.

5. **I do not have hospital financial data as there is not transparency, however it is estimated to be 51% of the average wholesale price in 2005 based on a report by the Congressional Budget Office published in 2005.[iii]**

It is possible that hospitals don't retain all of that discount in some of their contract pharmacy relationships. For specialty pharmacies there is a movement towards margin based contracts that could split the profits with the contract pharmacies. It is my understanding with the growth of margin based contracts for cancer drugs (specialty pharmacy) that is becoming more and more commonplace.

The amount of $10,000 is an estimate that is easy to understand an example where the discount is 50%. As a breast cancer specialist, many of the targeted therapies that I prescribe for metastatic breast cancer exceed that amount.

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6. Dr. Patt: In your testimony you state "qualifying hospitals sometimes refuse to see [vulnerable] patients."

    a. Please provide the Committee with a record or any other specific evidence that substantiates your assessment that patients are refused services because of the hospital's status as a qualifying entity in the 340B program.

6. 340B qualifying hospitals sometimes refuse to see vulnerable patients. I wouldn't suggest this is because they are 340B hospitals, but because qulification is only dependent on an inpatient metric of service, 340B qualifying entities could have little to no commitment to outpatient care for vulnerable patients.

7. Dr. Patt: In your testimony you state "[n]o one knows exactly how the incremental revenue of the 340B program is used without appropriate oversight and transparency, though data that we do have is troubling."

    a. Please provide the Committee with the specific data you are speaking to in this particular statement.

7. The data from previous Energy and Commerce Hearings articulates incremental revenue for hospital systems. Many of the systems report incremental revenues in excess of $100 million without substantiating how the money is used to serve vulnerable patient populations. In an article published by Nikpay et al earlier this year in JAMA Internal Medicine, hospitals participating in the 340B program with nonparticipants in 2015, participants had only a slightly higher burden of uncompensated care (4.10% vs 3.13%).[iv] The data that we do have suggests that many 340B qualifying entities have hundreds of millions of dollars of incremental revenue from this program, but that on average there is not a substantially higher commitment to uncompensated care in comparison to non 340b qualifying hospitals. In the absence of transparency, it is hard to quantify this in a more meaningful way.

8. Dr. Patt: In your testimony you state "[t]here are multiple uninsured patients with cancer who are county residents who are placed on a queue for months to be seen." Your testimony also detailed several stories that are quite concerning related to delays in care for treatment around the country.

    a. These are very concerning stories provided in your testimony to the Committee. Please provide the Committee with data substantiating these stories.

    b. Please provide the Committee with the statutory reference or additional data that contributes to delays or denials of care as a result of the functioning of the 340B program itself.

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c. Additionally, in these instances, was the treatment provided for these patients by yourself or by TX Oncology? (If these patients were not treated by TX Oncology, please indicate the rationale for not providing that treatment.)

8.

a. **Patient medical records are confidential and protected by HIPAA. In many instances in the medical records, there is mention of the difficulties in getting patients appointments for evaluation in the 340B qualifying entity's outpatient clinic.**

While I have stories from doctors in groups in other states, the majority of the stories I have are from Texas as I serve as a leader in my state wide practice and interact more with my statewide partners regarding the care of the patients we serve. Obviously, I know my own community best. Many of my stories are from Austin Texas as I am active in the medical community here and make rounds at the 340B hospital routinely, and see frequently the problems of lack of access to care.

In Kentucky a radiation oncologist discussed his patients challenges with me in caring for this patient with lung cancer. The patient characterized that he had seen the 340b hospital assoicated doctor, and that they were waiting for his insurance to come through to start treatment. Several months had passed and ultimately he presented to the non 340b associated doctor for definitive treatment, which the patient received. This is important on many levels, but mostly that when a patient presents with local lung cancer it is curable, and delays in treatment diminish the opportunity to cure. In Colorado, the medical oncologist informed me of the challenges in this patient with lymphoma even being seen by the University's 340B outpatient clinic. The patient was insured on Medicare part A, and the University hospital would not see or schedule the patient until he had Medicare part B. They were trying to have the patient evaluated for a clinical trial at the university, but he was refused treatment and ultimately died of his illness while waiting to be seen and evaluated for more treatment options.

In Longview Texas, my physician partners that practice there have characterized that the 340B hospital declines service for both uninsured and underinsured patients.

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In Austin, the two breast cancer patients I discuss are my own patients. They told me personally how they were refused treatment. They both are Austin residents and were uninsured. The metastatic colon cancer patient was a patient of my partner was treated in South Austin.

In Austin, the 35 year old pregnant metastatic colon cancer patient that waited several months for outpatient services at the 340B qualifying entity was under the care of my partner in Texas Oncology until ultimately after several months she was seen in the 340B qualifying entity outpatient clinic.

The 16 patients on the gynecologic oncology queue came up at our Access to Care meeting in April of 2017. As mentioned earlier among these questions, that is a meeting between the medical school, the hospital system and community collaborators. We were discussing this very issue of the struggle of getting uninsured patients appointments in the 340B entity's outpatient clinic and that many of these paitents had been in the queue for months. The gynecologic oncologist for Dell Medical School and Seton who sees patients in this clinic run by the 340B qualifying entity was present at the meeting. She offered that it wasn't that she didn't have room on her schedule, that she would be happy to see them. The CEO of Ascension Seton Medical Center Austin was also there at the meeting and she shared that Seton was contractually obligated to maintain spending for services at a certain benchmark based on a historical target year, and that had been exceeded. Because of this, these patients couldn't be seen. Later an agreement was forged giving Seton additional funds so these patients could be seen.

The lack of commitment to appropriate screening services in underserved populations has also been a struggle that I discuss in my testimony. As a cancer specialist, the best opportunities we have to cure cancer are when it is diagnosed early. Breast and colorectal cancer screening (in addition to other cancer screening) saves lives and frequently diminishes the need for additional complex therapy. I have only seen these services diminish for unfunded patients in my community. As a breast cancer specialist, and having led the charge of working with Seton and community stakeholders to optimize screening strategies throughout the community (as the network chair of the breast subcommittee for a decade), I have spent countless volunteer hours trying to help formulate plans to increase access to cancer screening. Despite this, earlier this year, the 340B hospital discontinued their outreach screening efforts for breast cancer screening

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Phone: (512) 427-9400 ♦ Fax: (512) 342-2723

alltogether, without an alternative plan to offer services with appropriate capacity and operations to overcome barriers of screening.[v]
The natural consequence of not offering appropriate screening for breast cancer, is that patients present with higher stage disease that is less likely to be cured. We see this is also true in our community where uninsured patients present with more advanced stage breast cancer, and when uninsured patients have cancer they are 50% more likely to die within a decade than patients who are insured.

It is my intent to characterize how incremental revenue could be used to improve care (and especially cancer care) for vulnerable populations, but it is not my intent to suggest that these issues have a singular solution as clearly they do not. As I pointed out in my testimony, Texas has a large burden of uninsured and underinsured patients and we all operate in an environment where we stretch limited resources. The barriers to care for vulnerable patients are complex and multifactorial. The sources of funding for uncompensated care are not singularly 340b. That said, in my opinion, this is exactly why having transparency and accountability are critical to maintaining the integrity of this program. If these funds are quantified and dedicated to serve vulnerable patients, the program would function more in alignment with its original intent to serve vulnerable patients.

b. I don't know of any data that delays and denials are a result of the 340B program, but if delays and denials are occuring routinely despite the presence of the 340B program, transparency and accountability might help us understand and rectify the current challenges in getting vulnerable patients access to care.

The Honorable Janice D. Schakowsky

1. Dr. Patt, in your testimony you state that "[m]any 'nonprofit' hospital executives have seven or eight figure annual salaries" and cite the Wall Street Journal's Million-Dollar Club as the group of executives you are speaking to.

    a. Please provide the Committee with evidence that shows how the 340B program directly contributed to significant salary increases, leading to the accumulation of "seven or eight figure" salaries of the individuals you reference.

1. I don't have direct evidence as I do not have access to hospital finances, though I note the correlation of the high incomes with some 340B qualifying not for profit entities. This does not imply causation. Without transparency we don't have data. If spending additional profits from the 340B program is not mandated statutorily, there is no transparency, vulnerable patients are

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being denied or delayed treatment, yet the CEO of a non-profit 340B hospital system has an annual income of $17.6 Million, it doesn't appear that all of the hundreds of millions of dollars of profit are being directed toward vulnerable patient care.

2. Dr. Patt, In your testimony you state "[b]ecause of the lack of transparency, oversight, and accountability, we can observe tremendous variability across the country in the philanthropic commitment of 340B hospitals in using additional revenue to enhance care for vulnerable patient populations."

    a. Please provide the Committee with a citation, source, and any other evidence substantiating your claim that such philanthropic variability exists because of a lack of transparency, oversight, and accountability of the 340B program.

2. There is clear evidence that philanthropic variability exists and there is no transparency and no statutory mandate to spend 340B profits to treat vulnerable patients. The variability we see today is not due to lack of transparency, as there is no transparency for programs that provide high levels of care to vulnerable patients nor is there transparency in programs that provide low levels of care to vulnerable patients. That said I do believe that mandates for transparency and accountability would improve the philanthropy of 340B qualifying entities because it would be visible to government and to the public. We also see evidence that 340B qualifying hospitals that entered in to the program from 1995-2004 provide far greater percent of uncompensated care than later entrants to the program (Uncompensated care burden 2.04 in early versus nonparticipants, 0.60 in intermediate versus nonparticipants, and 0.68 in late versus non participants.)[vi]

3. Dr. Patt, In your testimony you state "[b]ecause spending incremental 340B revenue on vulnerable patients is not mandated, some hospitals use these funds to build lavish new towers and enhance executive compensation."

    a. Please provide the Committee a citation, source, and any other evidence that shows how 340B savings are inappropriately and directly absorbed by hospital infrastructure/building funds and by greater executive compensatory allotments.

3.

In 2012 The Charlotte Observer led an investigation looking at non profit hospitals and found they directed profits to executive compensation and excessive spending on new buildings as well as new services and higher salaries. While this article wasn't about the 340B program specifically, it applies as it is a substantial profit center for many of these non profit entities and the article is about large non profit systems with high amounts of profit. As the 340B program contributes in excess of hundreds of millions of dollars to

many qualifying hospital systems, the 340B program can be a contributor to similar resource allocation choices.[vii]

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[i] Nikpay S, Buntin M, Conti RM. "Diversity of Participants in the 340B Drug Pricing Program for US Hospitals." *JAMA Intern Med*. 2018 Aug 1;178(8):1124-1127. doi: 10.1001/jamainternmed.2018

[ii] Winn AN, Keating NL, Trogdon JG, Basch EM,4, Dusetzina SB,. Spending by Commercial Insurers on Chemotherapy Based on Site of Care, 2004-2014. JAMA Oncol. 2018 Apr 1;4(4):580-581. doi: 10.1001/jamaoncol.2017.5544.

[iii] Congressional Budget Office. Prices for brand-name drugs under selected federal programs. June 2005. Available at: http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/64xx/doc6481/06-16-prescriptdrug.pdf.

[iv] Nikpay S, Buntin M, Conti RM. "Diversity of Participants in the 340B Drug Pricing Program for US Hospitals." *JAMA Intern Med*. 2018 Aug 1;178(8):1124-1127. doi: 10.1001/jamainternmed.2018

[v] Goldenstein, T "Mammograms or primary care? Future of Big Pink Bus up in the air." Austin American Statesman, July 27, 2018. https://www.mystatesman.com/news/local/mammograms-primary-care-future-big-pink-bus-the-air/ZFmxzOjNWBe5Fra3wTuM5N/

[vi] Nikpay S, Buntin M, Conti RM. "Diversity of Participants in the 340B Drug Pricing Program for US Hospitals." *JAMA Intern Med*. 2018 Aug 1;178(8):1124-1127. doi: 10.1001/jamainternmed.2018

[vii] Alexander, A, Garloch, K, and Neff J"Nonprofit Hospitals Thrive on Profits"The Charlotte Observer April 22, 2012

6204 Balcones Drive ♦ Austin, Texas 78731
Phone: (512) 427-9400 ♦ Fax: (512) 342-2723