

Questions for the Record

The Honorable Michael C. Burgess, M.D.

- 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 measure 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?**

At UC San Diego Health we are able to report our 340B estimated savings. In 2017, UC San Diego Health saved approximately \$85 million as result of the 340B program. We calculate our 340B savings by taking the best available non-340B price of covered outpatient drugs and subtract from this the estimated 340B acquisition costs for those drugs. We then add to this figure the benefit received from UC San Diego Health's arrangements with contract pharmacies. The final number is our 340B estimated savings.

All hospitals have different reporting and tracking systems and we cannot speak to the exact technical, administrative, or logistical reasons why other covered entities cannot report their savings. However, any reporting of 340B savings should be accompanied by additional information that explains the full extent of how covered entities use their 340B savings to benefit their communities and covered entities' charity care, undercompensated and uncompensated care, and bad debt. Additionally, requests that require extensive and specialized administrative reporting work will reduce the amount of 340B savings that we can use to provide service to patients and address community health needs.

The Honorable John Shimkus

- 1. On page 4 of your written testimony you noted that UCSD does not accept an “all in” clause from contract pharmacies. Can you explain what the means and why UCSD does will not accept that language? Do you think smaller entities have the ability to negotiate this same language? Does Congress need to intervene here?**

“All in” clauses often appear in contracts with retail pharmacy networks. They state that if the pharmacy opens a new store within, for example, the same metropolitan area as that in which the hospital is located, the hospital will accept that new pharmacy as part of its 340B contract pharmacy network. At UC San Diego Health, we try to create a focused contract pharmacy network. We contract with pharmacies in zip codes where we know our patients will be going to that pharmacy to have their outpatient prescriptions filled. We cannot speak on behalf of smaller entities regarding their ability to create contract pharmacy networks that track well to their patients' needs. However, our experience suggests that Congress does not need to intervene.

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?

UC San Diego's medical center delivered \$17 million in charity care and \$155 million in undercompensated care for indigent patients in publicly sponsored programs in the hospital's fiscal year ending June 30, 2017. UC San Diego Health directly invests 340B savings into a variety of programs and services that benefit low income, uninsured and vulnerable patient populations of its surrounding communities. UC San Diego Health pharmacies provide discounted or free outpatient drugs to patients who meet standard financial need criteria, following a case-by-case evaluation process, and who are not able to afford their medications. An example of such patient who benefited from UC San Diego Health's help affording his drugs was a patient who lost his employer-sponsored healthcare coverage. The 340B drug discount allowed the pharmacy to provide immunosuppressant and anticoagulant medication (Xarelto) at a discounted rate to the patient, so he could afford the drug until he was able to get new insurance. The patient saved \$750 in out-of-pocket costs because of UC San Diego Health's help absorbing the drug's cost.

UC San Diego Health also uses its 340B savings to provide other necessary medical services to the underserved. For example, presently, UC San Diego Health invests savings it generates from the 340B program in teams of physicians that make regular trips inland, to Imperial County, to deliver much needed medical care to underserved populations. The Census Bureau records that in 2016, 23.6 percent of Imperial County residents lived in poverty, and Imperial County residents' median household income was \$42,560.

UC San Diego Health also runs one of the most successful HIV/AIDS clinics in the country. The Owen Clinic is a contracted provider for the Ryan White HIV/AIDS Program and takes a whole-person care approach to treating patients with HIV or AIDS, offering a broad array of primary care and specialty care services, including addiction

counseling, nutrition counseling, and mental health care. Since the beginning of this year, the San Diego County Ryan White program changed its coverage of ambulatory health care services and stopped covering medications provided as part of medical, dental or psychiatric services. UC San Diego Health has continued to provide free or discounted medications to some patients, following an evaluation of their financial circumstances on a case-by-case basis.

Moreover, UC San Diego Health uses resources generated through its eligibility for the 340B discount to provide staff who can counsel patients at their bedsides before being discharged – i.e., a “meds to beds” program—on how to appropriately take their medications and improve their health outcomes. UC San Diego Health uses its 340B drug discount savings to invest in addressing patients’ medical needs early, rather than waiting until a patient experiences heightened medical complications and necessitates a costly inpatient stay. A great benefit of the 340B program is that the Health Resources and Services Administration’s (HRSA) program rules give UC San Diego Health the flexibility to decide how best to use the savings to serve the unique needs of its underserved patient populations.

However, it should be noted that UC San Diego Health operates the 340B program to assist our vulnerable patients, yet at the same time as a Medicare and Medicaid provider, UC San Diego Health is required to comply with federal Medicare and Medicaid rules that prohibit hospitals from routinely waiving co-pays or providing free or discounted services that are likely to induce Medicare or Medicaid beneficiaries to return for other services payable by Medicare or Medicaid (commonly known as the prohibition against beneficiary inducement).

The Honorable Leonard Lance

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

HRSA needs to implement the 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties regulation. This regulation’s implementation has been delayed numerous times by HRSA. When implemented, UC San Diego Health can more accurately calculate its savings under the 340B program. Currently, covered entities have no ability to verify ceiling prices and cannot determine if they are being charged the correct amount for these drugs. Without the added transparency of manufacturers’ drug prices, we can only estimate savings, rather than exactly identify differences between the paid price under 340B and the next best price.

Otherwise, we believe HRSA is efficiently administrating the 340B program, which provides critical support to UC San Diego Health to be able to provide more comprehensive services to the most vulnerable patients in our community.

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

UC San Diego Health works with HRSA in administration of the 340B program and takes very seriously its responsibility to be a good steward of program rules and guidelines. In addition to following such rules, UC San Diego Health has put into effect numerous internal and external practices to further ensure and promote compliance.

For example, at UC San Diego Health, we employ dedicated pharmacy staff to conduct internal audits each month of a random sample of 340B transactions from our hospital facilities and child sites. Audits include both in-house pharmacies and contract pharmacies, to verify that those prescriptions meet all of the HRSA requirements to be eligible for a 340B discount. The results of those internal audits are formally reported to the pharmacy department leadership on a quarterly basis and to the Executive Steering Committee for UC San Diego Health at least twice per year. This is done to ensure that any detected discrepancies or deficiencies are investigated and corrected in a timely way, and that any safeguards needed to prevent re-occurrence of any incident are put into place. UC San Diego Health also routinely hires an outside auditor to conduct an annual review of our 340B program compliance. We also regularly provide continuing education on 340B rule clarifications to our 340B compliance staff and pharmacy personnel who work directly with patient prescriptions at the prescription counter. Additionally, UC San Diego Health requires that any contract pharmacies that we work with meet the same standards for compliance.

The Honorable H. Morgan Griffith

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

UC San Diego Health has participated in the 340B program since its inception in 1992. In 2011 we acquired the San Diego Cancer Center, an outpatient cancer center, which we subsequently registered as a child site in the 340B program, in accordance with HRSA rules.

Child sites of 340B-eligible hospitals have been allowed to participate in the 340B program since 1994, and there are specific rules and requirements that must be met in order for a hospital outpatient facility to be registered as a child site. Under HRSA program rules, a 340B-eligible hospital's off-site outpatient facility is eligible to be registered as a child site if it is an integral part of the hospital, as reflected by its being listed as a reimburseable facility on the hospital's most recently filed Medicare cost report. Each clinic, service or department of the hospital that is located off-site from the parent hospital, regardless of whether such clinics or services are in the same building as

each other, must be registered separately as a child site in order to be eligible for the 340B program pricing.

Mainly, the growth in child sites for UC San Diego Health can be attributed to changes in HRSA's guidance on registering each "child site" in June 2014. This artificial growth was also noted in the 2018, Energy and Commerce Committee Report, Review of the 340B Drug Pricing Program. The report highlighted that growth in the 340B program can be attributed to the 2014 HRSA guidance that changed how child sites must register. The report states "part of the growth may be artificial because many hospitals began newly registering as child sites facilities that had previously been in operation."

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?**

Because the 340B program provides critical support for so many of the programs and services we provide to our most vulnerable patients, we take audits by HRSA very seriously and work to ensure comprehensive program compliance at UC San Diego Health. When HRSA finds deficiencies in compliance, we immediately work to make improvements. For example, in our last HRSA audit (for fiscal year 2014), HRSA found that UC San Diego Health had two National Provider Identifier (NPI) numbers that were missing from the HRSA Medicaid Exclusion file, which is the mechanism that HRSA uses to help covered entities and State Medicaid programs prevent duplicate discounts – that is, the collection of 340B discounts for drugs subject to Medicaid rebates. UC San Diego Health worked with California State Department of Health Care Services (which administers the Medicaid program in California) to identify any duplicate discounts that occurred and to repay all of the affected manufacturers. Since that finding, UC San Diego Health also has implemented a process to annually verify that all of the appropriate NPI numbers are included in the Medicaid Exclusion File to prevent a similar administrative error from occurring again.

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

UC San Diego Health believes HRSA is effective in assessing noncompliance of covered entities in the 340B program. For UC San Diego Health, HRSA's audit system has been successful in seeking to ensure program integrity and compliance with rules and

guidelines. However, we cannot speak on what HRSA practices do or do not work for other 340B covered entities.

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?

We use our 340B savings in a variety of ways, including operating primary and specialty care clinics for vulnerable patient populations, like our renowned HIV clinic as well as a Hepatitis C clinic, paying for a mobile team of physicians to travel to remote El Centro in Imperial County to treat underserved patients, and providing certain patients who meet prescribed criteria with free or discounted prescription drugs. HRSA rules allow us to decide how we use our 340B savings. Our own pharmacists directly interact with patients at our in-house pharmacy. Consequently, we've decided that the in-house pharmacy is the best setting at which to provide drug discounts for select patients who meet the standard financial need criteria established by UC San Diego Health's pharmacies.

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

Contract pharmacy arrangements allow UC San Diego Health to derive benefits from the 340B program, while allowing our patients to get their prescriptions filled at pharmacy locations most convenient to them. We invest the 340B savings, which includes the benefits generated from our relationships with contract pharmacies, to further our mission as a public academic medical center to deliver outstanding patient care through commitment to the community, groundbreaking research and inspired teaching, by providing discounted or free outpatient drugs to patients who meet standard financial need criteria, following a case-by-case evaluation process, and who are not able to afford their medications. An example of such patient who benefited from UC San Diego Health's help affording his drugs was a patient who lost his employer-sponsored healthcare coverage. The 340B drug discount allowed the pharmacy to provide immunosuppressant and anticoagulant medication (Xarelto) at a discounted rate to the patient, so he could afford the drug until he was able to get new insurance. The patient saved \$750 in out-of-pocket costs because of UC San Diego Health's help absorbing the drug's cost.

UC San Diego Health also uses its 340B savings to provide other necessary medical services to the underserved. For example, presently, UC San Diego Health invests savings it generates from the 340B program in teams of physicians that make regular trips inland, to Imperial County, to deliver much needed medical care to underserved populations. The Census Bureau records that in 2016, 23.6 percent of Imperial County

residents lived in poverty, and Imperial County residents' median household income was \$42,560.

UC San Diego Health also runs one of the most successful HIV/AIDS clinics in the country. The Owen Clinic is a contracted provider for the Ryan White HIV/AIDS Program and takes a whole-person care approach to treating patients with HIV or AIDS, offering a broad array of primary care and specialty care services, including addiction counseling, nutrition counseling, and mental health care. Since the beginning of this year, the San Diego County Ryan White program changed its coverage of ambulatory health care services and stopped covering medications provided as part of medical, dental or psychiatric services. UC San Diego Health has continued to provide free or discounted medications to some patients, following an evaluation of their financial circumstances on a case-by-case basis.

Moreover, UC San Diego Health uses resources generated through its eligibility for the 340B discount to provide staff who can counsel patients at their bedsides before being discharged – i.e., a “meds to beds” program—on how to appropriately take their medications and improve their health outcomes. UC San Diego Health uses its 340B drug discount savings to invest in addressing patients' medical needs early, rather than waiting until a patient experiences heightened medical complications and necessitates a costly inpatient stay. A great benefit of the 340B program is that the Health Resources and Services Administration's (HRSA) program rules give UC San Diego Health the flexibility to decide how best to use its 340B savings to serve the unique needs of its underserved patient populations.

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

We believe in HRSA's current administration of the 340B Drug Pricing Program with regard to patient eligibility and drug discounts.

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?

To calculate 340B savings at UC San Diego Health, we take the best available non-340B prices or other estimated acquisition costs for covered outpatient drugs and subtract from the estimated 340B acquisition costs for those drugs. We then add to this figure the benefit received from UC San Diego Health's arrangements with contract pharmacies. The final calculated figure is our estimated 340B savings. We can review our estimated 340B savings for the previous year and allocate those savings to support the operating

costs of our "meds to bed" program, clinics, supplying mobile teams of physicians to travel to see patients in Imperial County, and offering some drug discounts.

Our 340B savings do not go into a general fund like would occur if we received a payment and deposited it into a general fund. We do not receive a tangible payment from manufacturers as a result of the 340B program. Instead we receive price discounts that are integrated into our invoiced prices through the wholesaler or manufacturer invoices.

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?

HRSA does not require covered entities to report their 340B savings or to keep track of 340B savings through any other mechanism.

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

HRSA does not require covered entities to report how they use their 340B revenue.

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

At UC San Diego Health, we strongly believe we are using our 340B revenue for the original intended purposes of the program, "to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." We cannot speak to other 340B covered entities, but UC San Diego Health pharmacies provide discounted or free outpatient drugs to patients who meet standard financial need criteria, following a case-by-case evaluation process, who are not able to afford their medications. An example of such patient who benefited from UC San Diego Health's help affording his drugs was a patient who lost his employer-sponsored healthcare coverage. The 340B drug discount allowed the pharmacy to provide immunosuppressant and anticoagulant medication (Xarelto) at a discounted rate to the patient, so he could afford the drug until he was able to get new insurance. The patient saved \$750 in out-of-pocket costs because of UC San Diego Health's help absorbing the drug's cost that was possible from 340B benefits.

UC San Diego Health also uses its 340B revenue to provide other necessary medical services to the underserved. For example, presently, UC San Diego Health invests revenue it generates from the 340B program in teams of physicians that make regular trips inland, to Imperial County, to deliver much needed medical care to underserved populations. The Census Bureau records that in 2016, 23.6 percent of Imperial County residents lived in poverty, and Imperial County residents' median household income was \$42,560.

UC San Diego Health also runs one of the most successful HIV/AIDS clinics in the country. The Owen Clinic is a contracted provider for the Ryan White HIV/AIDS Program and takes a whole-person care approach to treating patients with HIV or AIDS, offering a broad array of primary care and specialty care services, including addiction counseling, nutrition counseling, and mental health care. Since the beginning of this year, the San Diego County Ryan White program changed its coverage of ambulatory health care services and stopped covering medications provided as part of medical, dental or psychiatric services. UC San Diego Health has continued to provide free or discounted medications to some patients, following an evaluation of their financial circumstances on a case-by-case basis.

Moreover, UC San Diego Health uses resources generated through its eligibility for the 340B discount to provide staff who can counsel patients at their bedsides before being discharged – i.e., a “meds to beds” program—on how to appropriately take their medications and improve their health outcomes. UC San Diego Health uses its 340B drug discount savings to invest in addressing patients’ medical needs early, rather than waiting until a patient experiences heightened medical complications and necessitates a costly inpatient stay. A great benefit of the 340B program is that the Health Resources and Services Administration’s (HRSA) program rules give UC San Diego Health the flexibility to decide how best to use the savings to serve the unique needs of its underserved patient populations.

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

As noted above, UC San Diego Health pharmacies provide discounted or free outpatient drugs to patients who meet standard financial need criteria, following a case-by-case evaluation process, and who are not able to afford their medications. An example of such patient who benefited from UC San Diego Health’s help affording his drugs was a patient who lost his employer-sponsored healthcare coverage. The 340B drug discount allowed the pharmacy to provide immunosuppressant and anticoagulant medication (Xarelto) at a discounted rate to the patient, so he could afford the drug until he was able to get new insurance. The patient saved \$750 in out-of-pocket costs because of UC San Diego Health’s help absorbing the drug’s cost that was possible from 340B benefits.

However, it should be noted that UC San Diego Health operates the 340B program to assist our vulnerable patients, yet at the same time as a Medicare and Medicaid provider. UC San Diego Health is required to comply with federal Medicare and Medicaid guidance which prohibits hospitals from waiving co-pays or providing free services as an inducement to federal healthcare program beneficiaries to return for other services (commonly known as the prohibition against inducement).

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?

At UC San Diego Health we are confident that we can report our 340B savings. In 2017, we estimate that UC San Diego medical center saved \$85 million. Any reporting of 340B savings needs to be simple, standardized, and capture the full extent of what covered entities do with their 340B savings along with covered entities' undercompensated and uncompensated care, bad debt, and charity care. Requests that require extensive and specialized administrative reporting work will reduce the amount of 340B savings that we can use to provide service to patients and address community health needs.

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?

UC San Diego Health cannot speak to what services are provided at other hospitals, whether they are 340B covered entities or not. However, UC San Diego Health is a public academic medical center that qualifies as both a Medicaid Disproportionate Share Hospital (DSH) and Medicare DSH hospital and offers a broad array of specialized services. For example, as a premier provider of tertiary and quaternary services, we provide the region's first Level 1 Trauma Center and its only Regional Burn Center. We also have the region's only National Cancer Institute (NCI)-designated Comprehensive Cancer Center. In addition, we house two Comprehensive Stroke Centers, multi-organ transplant programs, and California's only advanced certification program for chronic kidney disease care.

UC San Diego Health also operates one of the most successful HIV/AIDS clinics in the country. The Owen Clinic is a contracted provider for the Ryan White HIV/AIDS Program and takes a whole-person care approach to treating patients with HIV or AIDS, offering a broad array of primary care and specialty care services, including addiction counseling, nutrition counseling, and mental health care. Since the beginning of this year, the San Diego County Ryan White program changed its coverage of ambulatory health care services and stopped covering medications provided as part of medical, dental or psychiatric services. UC San Diego Health has continued to provide free or discounted medications to some patients, following an evaluation of their financial circumstances on a case-by-case basis.

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

Since the 340B Drug Pricing Program was enacted in 1992, Congress has included public DSH hospitals that meet certain criteria, like UC San Diego Health, as covered entities.

These hospitals treat high numbers of Medicaid and other low-income patients, and thus are ideally placed to fulfill the intent of the program to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services. The flexibility provided in the 340B program allows UC San Diego Health to provide charity care, uncompensated and undercompensated care, as well as cover the bad debt of patients who cannot pay the full price of expensive medical services. Any additional metrics intended to capture a covered entity's commitment to the program must include the full extent of what covered entities do with their 340B savings, including covered entities' undercompensated and uncompensated care, bad debt, and charity care.

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?

As noted above, UC San Diego Health pharmacies provide discounted or free outpatient drugs following a case-by-case evaluation process to patients who meet standard financial need criteria and who are not able to afford their medications. UC San Diego Health provides free care for qualified patients with incomes at or below a specified level of the federal poverty guidelines if those patients complete an application and provide supporting documentation as requested to demonstrate their financial need.

An example of such patient who benefited from UC San Diego Health's help affording his drugs was a patient who lost his employer-sponsored healthcare coverage. The 340B drug discount allowed the pharmacy to provide immunosuppressant and anticoagulant medication (Xarelto) at a discounted rate to the patient, so he could afford the drug until he was able to get new insurance. The patient saved \$750 in out-of-pocket costs because of UC San Diego Health's help supplementing the drug's cost, made possible through 340B benefits.

However, it should be noted that UC San Diego Health operates the 340B program to assist our vulnerable patients, and yet at the same time as a Medicare and Medicaid provider, UC San Diego Health is required to comply with federal Medicare and Medicaid rules that prohibit hospitals from routinely waiving co-pays or providing free or discounted services that are likely to induce Medicare or Medicaid beneficiaries to return for other services payable by Medicare or Medicaid (commonly known as the prohibition against beneficiary inducement).

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

UC San Diego Health does not track patient-level data regarding use of pharmaceutical companies' patient assistance programs across all part of its clinical enterprise and

therefore cannot accurately determine the percentage of the patients that UC San Diego Health serves that are receiving free medicine from those programs. UC San Diego Health does have patient-level data for the patients treated at our infusion centers and approximately 2.4% of those patients receive free drugs from a patient assistance program offered by the pharmaceutical industry.

The Honorable Earl. L. "Buddy" Carter

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

UC San Diego's medical center delivered nearly \$17 million in charity care and \$155 million in undercompensated care for indigent patients in publicly sponsored programs in the hospital's fiscal year ending June 30, 2017. These amounts are reported on the medical center's audited financial statements. The UC San Diego medical center estimates the costs of charity care provided to patients who meet criteria under the UC San Diego Health financial assistance policy for free or discounted care, as well as the costs of care provided to patients without insurance who have not completed the formal process of applying for charity but are considered indigent and are presumed to be eligible for charity care. Included in the estimated cost of charity care of nearly \$17 million is \$1.9 million in estimated cost of care provided to self-pay indigent patients presumed to qualify for charity care. The \$155 million in undercompensated care represents the difference between the amount of reimbursement paid by publicly sponsored programs, including Medi-Cal (California's Medicaid program), county health plans, and other public insurance programs available for indigent patients, and the estimated cost of the services provided to those indigent patients. The \$155 million does not include the amounts of undercompensated care provided to Medicare patients or bad debt.

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

Yes, as we understand this question for purposes of participating in the 340B program, child sites are required to abide by the same HRSA program rules as their parent sites.

The Honorable Frank Pallone, Jr.

1. One of the bills before us—the Protecting Safety-Net 340B Hospitals Act—would raise the DSH percentage for hospital eligibility to such a degree that more than half of all hospitals would be eliminated from the program—including 50 such hospitals in nearly every member of this Committee's districts. The premise for this legislation is presumably that the program is growing at an explosive rate.

a. Dr. Daniels—do you believe that we can improve access to care for vulnerable patients through 340B without diminishing or cutting the program? Is the 340B

program growing at an explosive rate?

I believe that we are already improving access to care for vulnerable patients through the 340B program. UC San Diego Health uses the savings generated by the 340B program to improve access to care and reduce costs to vulnerable, low-income patients. Specifically, UC San Diego Health pharmacies provide discounted or free outpatient drugs to patients who meet standard financial need criteria, following a case-by-case evaluation process, and who are not able to afford their medications. An example of such patient who benefited from UC San Diego Health's help affording his drugs was a patient who lost his employer-sponsored healthcare coverage. The 340B drug discount allowed the pharmacy to provide immunosuppressant and anticoagulant medication (Xarelto) at a discounted rate to the patient, so he could afford the drug until he was able to get new insurance. The patient saved \$750 in out-of-pocket costs because of UC San Diego Health's help absorbing the drug's cost.

UC San Diego Health also uses its 340B savings to provide other necessary medical services to the underserved. For example, presently, UC San Diego Health invests savings it generates from the 340B program in teams of physicians that make regular trips inland, to Imperial County, to deliver much needed medical care to underserved populations. The Census Bureau records that in 2016, 23.6 percent of Imperial County residents lived in poverty, and Imperial County residents' median household income was \$42,560.

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Moreover, UC San Diego Health uses resources generated through its eligibility for the 340B discount to provide staff who can counsel patients at their bedsides before being discharged – i.e., a “meds to beds” program—on how to appropriately take their medications and improve their health outcomes. UC San Diego Health uses its 340B drug discount savings to invest in addressing patients' medical needs early, rather than waiting until a patient experiences heightened medical complications and necessitates a costly inpatient stay. A great benefit of the 340B program is that the Health Resources and Services Administration's (HRSA) program rules give UC San Diego Health the flexibility to decide how best to use the savings to serve the unique needs of its underserved patient populations.

Any actions to diminish or reduce the benefits of the program will have a detrimental impact on UC San Diego Health's ability to provide comprehensive services to vulnerable patient populations.

Based on our experience participating in the 340B program and our observations of the program since its inception, we do not believe that the program is growing at what is described as an "explosive rate." As noted in the 2018 Energy and Commerce Committee Report, Review of the 340B Drug Pricing Program, growth in the program can be attributed to the 2014 HRSA guidance that changed how child sites must be registered. The report states "part of the growth may be artificial because many hospitals began newly registering as child sites facilities that had previously been in operation." Additionally, the last major growth of the 340B program came when Congress expanded 340B program participation to critical access hospitals, sole community hospitals, and rural referral centers as covered entities through the Affordable Care Act (ACA).

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

The 340B discount attaches only to drugs dispensed by covered entities that meet the 340B Program's eligibility criteria to patients that meet a number of criteria established by HRSA. Please see the attached UC San Diego Health flowchart (Exhibit 1) which illustrates the many steps that must be satisfied for an outpatient drug to receive the 340B discount. If the hospital or its child site meet the eligibility criteria to participate in the 340B program, and the prescribing provider and the patient filling the prescription meet every step on this flowchart, then the hospital can collect the 340B discount on that drug. At the end of a year, we can estimate closely (not having full access to the ceiling prices of the participating 340B pharmaceutical manufacturers) what we would have spent absent the discount, but we don't get a check for the amount. The discount lowers the purchase price for a given drug each time the steps in the attached flowchart are fulfilled. At the end of the year, we can approximate what we would have generated in 340B savings from the operation of the

discount, looking across all the purchases in which a drug qualified for the 340B discount. We cannot predict what our 340B savings will be in advance, but we can look back and see in a year how much we saved by not having to purchase a drug at the GPO price or other commercially available price versus getting the lower 340B discount price.

At UC San Diego Health, we use the 340B program to service low-income patients. Our 340B generated savings allow us to make numerous investments in vulnerable patient populations. For example, presently, UC San Diego Health invests savings it generates from the 340B program in teams of physicians that make regular trips inland, to Imperial County, to deliver much needed medical care to underserved populations. The Census Bureau records that in 2016, 23.6 percent of Imperial County residents lived in poverty, and Imperial County residents' median household income was \$42,560.

UC San Diego Health also runs one of the most successful HIV/AIDS clinics in the country. The Owen Clinic is a contracted provider for the Ryan White HIV/AIDS Program and takes a whole-person care approach to treating patients with HIV or AIDS, offering a broad array of primary care and specialty care services, including addiction counseling, nutrition counseling, and mental health care. Since the beginning of this year, the San Diego County Ryan White program changed its coverage of ambulatory health care services and stopped covering medications provided as part of medical, dental or psychiatric services. UC San Diego Health has continued to provide free or discounted medications to some patients, following an evaluation of their financial circumstances on a case-by-case basis.

Moreover, UC San Diego Health uses resources generated through its eligibility for the 340B discount to provide staff who can counsel patients at their bedsides before being discharged – i.e., a “meds to beds” program—on how to appropriately take their medications and improve their health outcomes. UC San Diego Health uses its 340B drug discount savings to invest in addressing patients' medical needs early, rather than waiting until a patient experiences heightened medical complications and necessitates a costly inpatient stay. A great benefit of the 340B program is that the Health Resources and Services Administration's (HRSA) program rules give UC San Diego Health the flexibility to decide how best to use the savings to serve the unique needs of its underserved patient populations.

- 3. 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?

HRSA's continual delay of the 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties regulation puts UC San Diego Health, and other 340B covered entities, at a stark disadvantage when contracting with participating 340B pharmaceutical manufacturers. Currently, covered entities have no ability to verify ceiling prices and cannot determine if they are being charged the correct amount for outpatient drugs on the 340B formulary. Without the added transparency of participating manufacturers' drug prices, we can only estimate savings, rather than exactly identify differences between the paid price under 340B and the next best price. When implemented, UC San Diego Health can more accurately calculate its savings under the 340B program.

4. 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.

In the first four months after the January 1, 2018 implementation of the nearly 30 percent cut in Medicare Part B reimbursement to hospitals for drugs acquired through the 340B program (i.e., through April 30, 2018), UC San Diego Health experienced an approximately \$3.6 million reduction in reimbursement for the patients we treated using drugs acquired under the 340B program. Even after taking into account the relatively small increase in Medicare payment rates for other hospital outpatient services in calendar year 2018, UC San Diego Health anticipates that it will lose several million dollars in Medicare reimbursement for this calendar year alone. UC San Diego Health is concerned that the financial impact of the nearly 30 percent cut in Medicare Part B reimbursement for drugs purchased under the 340B program will restrict UC San Diego Health's ability to provide some of the services we offer our underserved patient communities. Any efforts in rulemaking or legislation to scale back the 340B Drug Pricing Program would be detrimental to our patients and the patients of so many safety net providers across the country, and we will be forced to make difficult decisions about how to maintain those vital services.

5. The recent GAO report confirms that contract pharmacies play an essential role in helping uninsured and low-income patients get needed care, including, but not limited to, prescription drugs. However, GAO notes that HRSA needs to provide

additional oversight over the contract pharmacies. While the agency did not agree with all of GAO's recommendations, there were important points made on certain areas for improvement.

- a. Dr. Daniels, can you describe how UCSD uses its contract pharmacy arrangements to increase access for patients? What types of contract pharmacies does UCSD have? What oversight measures are in place in order to maintain compliance with program regulations? How does UCSD make the decision to enter into a contract pharmacy arrangement?**

UC San Diego Health selects the contract pharmacies with which it will contract based on those with locations most accessed by our patients. UC San Diego Health has in recent years reduced its contract pharmacies from 116 in 2016 to 63 today. UC San Diego Health invests fees generated by contract pharmacies in providing medical services and discounted prescription drugs to underserved patient populations.

UC San Diego Health requires that any contract pharmacies that we work with comply with HRSA rules and guidance. We have two full time pharmacy personnel to oversee our 340B program, perform internal audits and maintain compliance. Monthly audits are performed for all areas that use and purchase 340B drugs including contract pharmacies. Audit results along with action plan for any variances are reported to the Pharmacy Leadership Committee on a quarterly basis and to the Executive Steering Committee on a biannual basis. In addition, we also conduct a comprehensive external audit on an annual basis from independent third-party consultants.

We have mapped out where our patients go to fill their prescriptions, and we have entered into contract pharmacy arrangements with pharmacies located within zip codes that are accessible to most of our patients. For example, Hillcrest Pharmacy, one of UC San Diego Health's contract pharmacies is located in a neighborhood accessible to many of our HIV patients. The Hillcrest Pharmacy offers services that are highly valued by our HIV patients. UC San Diego Health also does not accept "all in" contractual clauses from pharmacy chains which would require us to contract with any future pharmacy erected in the chain's San Diego area network, regardless of whether these new pharmacies are typically used by UC San Diego Health patients.