Ronald A. Paulus, MD
President and CEO

November 21, 2017

The Honorable Greg Walden, Chairman
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515-6115

RE: Additional Questions for the Record

Dear Chairman Walden:

Thank you for the opportunity to provide additional information regarding Mission Health's participation in the 340B Drug Pricing Program. Our responses to The Honorable Morgan Griffith's questions that were provided in your November 7, 2017 letter are attached.

We appreciate your allowing Mission Health to provide the Committee with additional information and to share our thoughts on key policy issues both now, and in the future.

Sincerely,

Ronald A. Paulus, M.D.
President and Chief Executive Officer
Mission Health System, Inc.

cc: The Honorable Diane DeGette, Ranking Member, Subcommittee on Oversights and Investigation

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Additional Questions for the Record

The Honorable Morgan Griffith

1. Can you provide your opinion as to why the Disproportionate Share Hospital (DSH) metric, which measures Medicare and Medicaid inpatient stays, is or is not appropriate for use in an outpatient drug program targeting underinsured and uninsured patients?

Even though the metric measures inpatient care, the Disproportionate Share Hospital (DSH) metric is appropriate for use in the 340B program, especially with respect to urban DSH and safety net hospitals.

The DSH metric identifies hospitals that provide inpatient services to a larger number of Medicaid and low-income Medicare/SSI patients than other hospitals (as opposed, for example, to hospitals that more routinely provide stabilizing treatment and then transfer or refer those patients to other medical centers for acute care). In other words, the DSH metric percentage identifies hospitals that provide a disproportionate share of inpatient care that is reimbursed below the actual cost of providing that care and correspondingly, identifies those hospitals that consistently serve a larger number of the most vulnerable patients in the community.

These vulnerable patients are often in need of complex care, require more resources, and are almost universally unable to afford the care that they need. The DSH metric, will imperfect, provides direct insight into the culture of the hospital and its commitment to caring for vulnerable, uninsured, and underinsured patients; that culture and philosophy of caring is unlikely to differ between inpatient and outpatient services. Importantly, those unique outpatient settings that are similarly dedicated to providing care to the most vulnerable (e.g., Rural Health Centers) separately qualify for the program.

There is no perfect metric, and perfect is often the enemy of the good. The DSH metric effectively identifies those hospitals providing higher amounts of care to inherently vulnerable populations, as is consistent with the goals of the 340B Program. The data used to support the calculation is readily available to the Health Resources and Services Administration (HRSA) and results in a reliable and clear metric for determining access to the 340B Program.

2. During the hearing, it was clear that covered entities use different definitions for "charity care" and report different data on Medicare forms. Can you provide (1) the data your hospital uses to track charity care, (2) the amount of charity care provided, based on this data, and (3) whether you think this type of charity care metric should be applied uniformly across the program?

Mission has adopted and follows financial assistance policies that are aimed at providing relief from medical expenses to patients and families without adequate resources to pay. The policies apply to services provided in every Mission Health location. Mission provides free care

for those up to 200% of the Federal poverty guidelines and a sliding-scale discount for those between 200-300% of the Federal poverty guidelines. Patients applying for and meeting criteria as identified in our policies are tracked in our patient accounting/billing system, along with all other patients. **Those patient charges are ultimately converted to "cost" for the purposes of IRS Form 990, Schedule H reporting. Also, account balances of patients who fail to provide proof of income and are unable to pay their expenses are classified as "bad debt," not "charity care," even though they may have met federal poverty guidelines.**

As a tax-exempt, non-profit organization, Mission tracks its charity care and then reports the information on IRS Form 990, Schedule H each year. It may be reasonable for all 340B eligible hospitals to report charity care using the same methodology (cost vs. charges for example). Since the IRS Form 990, Schedule H definition of "charity care" reported on the basis of cost is a standard already used by tax-exempt hospitals, using this vehicle (or at least its underlying metrics and calculations) would have the added benefit of reducing the burden of creating new or additional reporting tools and definitions.

3. Would you support a new 340B program requirement that mandates a certain level of charity care?

No, we would not. While charity care is obviously an important part of the discussion, data regarding bad debt, Medicaid/Medicare under reimbursement, and community benefit tell the important and much larger story of how hospitals use 340B savings to meet the intent of the 340B Program—to stretch scarce federal resources as far as possible and provide more comprehensive services. Hospitals like Mission are critical public health resources for the communities they serve, and, as such, complete a publicly available Community Health Needs Assessment and Plan every three years to address the health needs of the community. Steps taken, including financial commitments to support elements of the plan, are reported on IRS Form 990 each year.

For example, Mission provided $1 million toward the establishment of a walk-in, urgent care clinic for those with behavioral health needs, including a 24-hour urgent care unit, a mobile crisis management team, a community pharmacy, and outpatient services. Mission Health's contribution was matched by a grant from the North Carolina Department of Health and Human Service totaling almost $1 million more. This center was established in collaboration with local officials, law enforcement, local behavioral health and safety net providers, a behavioral health managed care organization, and the local chapter of NAMI (National Alliance on Mental Illness). This center is vital in addressing the behavioral health and opioid crisis in our region. This contribution is not reflected as "charity care," but it is an example of how we serve our region through targeted community benefit programming. Likewise, our Medication Assistance Program is invaluable to patients but is not included in our projected $42 million in charity care at cost for FY 2017.

Another example of care that would not be captured in reporting "charity care" is our ownership in an organization operating a local, free medical clinic and free pharmacy to qualifying patients. Mission's financial support of the clinic exceeded $2 million from 2012-2016 and in-kind medical services (including labs, radiology, and medication expenses) exceeded over $2.7 million during the same time period. This work is reported on the community benefit line of IRS Form 990 Schedule H, but is not included on the "charity care" line of Schedule H.

These are only three of many examples where vital services to our community are not captured in the "charity care" definition on IRS Form 990, Schedule H. By creating 340B access solely based on a "charity care" analysis, hospitals that are doing critical work for their communities may not qualify even though they clearly provide important services and programs of the type intended to be supported by the 340B program.

4. Does your hospital have a policy to treat anyone regardless of ability to pay?

Yes, we do. Mission Health treats any patient without regard to the ability to pay, period.

5. During the hearing, you suggested that Congress examine the Schedule H/Community Benefit on IRS Form 990, stating that the information reported on that form may provide "opportunities to define and identify" appropriate reporting requirements. Can you provide more detail about how this IRS form may be used for mandatory reporting in the 340B program?

Schedule H of IRS Form 990 is designed to quantify, in a standardized manner, the community benefit provided by hospitals to support tax-exempt status. We encourage the Committee to build on Schedule H as a component of, or as the standardized reporting tool for, 340B hospitals. Seventy-five percent of 340B savings is realized by hospitals. Including transparent reporting of total 340B savings and comparing those savings in a fair and transparent manner to community benefit contributions by hospitals offers a specific, relatively easy way to track whether hospitals are using the savings in ways that support the intent of the 340B Program—while allowing hospitals to do so in ways that best serve the individual needs of their patients and communities. In addition, because it already exists for a similar purpose, it streamlines the regulatory process and builds upon prior work.

a. **Would total unreimbursed care be an appropriate measure of charity care or a separate 340B eligibility metric?**

As noted above, we do not agree that that charity care, combined with unreimbursed Medicaid/Medicare costs and bad debt alone, adequately captures and tells the overall story for defining a hospital's community benefit. It is necessary, but not sufficient.

We do support the use of IRS Form 990, Schedule H, a modification to that Schedule, or a tool based on that Schedule for 340B eligible hospitals to capture, in a standardized manner, the total community benefit of the organization. Once consistent data is captured, that same data could be analyzed by this Committee in the future to help articulate sound 340B policy.

6. Would you support new mandatory reporting /tracking requirements for 340B hospitals to achieve more consistency with respect to program savings?

We support the use of a modified IRS Form 990, Schedule H for hospitals to report 340B savings and contract pharmacy value. 340B savings for hospital-based locations can be obtained through wholesaler reporting data (defined as the difference between the 340B price and GPO price), and the value contribution of contract pharmacies (defined as revenue less dispensing fees less cost of goods sold less 340B vendor fees) is available through the hospital 340B vendor.

7. In your written testimony, you noted that you had a compliance issue with patient eligibility because the patient definition has "been elusive and fraught with lack of regulatory clarity." How would you propose to strengthen the patient definition?

The issuance of clear, statutory language supported by a formal and consistent regulatory and/or rule-making process regarding the "patient" definition would strengthen the 340B Program and help 340B hospitals meet program requirements in a consistent manner. There have been no significant modifications to the 340B statutes over the past 25 years. During this time, HRSA has, due to the state of the applicable statutes, at times dictated or ushered compliance through the issuance of "frequently asked questions" posed on the 340B website and/or through audit findings (instead of issuing regulations and/or through rulemaking), leading to varying interpretations of permissible/impermissible use across the 340B program. This process has made it more difficult to optimally achieve compliance in an already complex program.

By way of example, 340B providers have asked the question as to whether, in owned or contracted community pharmacies, a Medicaid Managed Care patient is eligible for 340B-priced medications. In multiple forums, the verbal answer from HRSA has been that only fee-for-service Medicaid duplicate discounts are prohibited, and a Medicaid Managed Care patient is, therefore, 340B eligible. The Apexus website "frequently asked questions" does not include an answer to the question. The "eligible patient definition" in this situation is not clear, and, accordingly, hospitals must make a decision that could ultimately result in audit findings. Situations like this example are what Mission references as a lack of regulatory clarity, and it is a clear opportunity for improvement.

The "patient" definition concept was meant to ensure that prescriptions qualifying for 340B discounts are adequately tied to services provided by or in relation to a qualifying or eligible

340B hospital and its providers across the continuum, to support those hospitals in their efforts to serve vulnerable populations. This intent should be preserved. This committee might also consider updates to the language to better reflect how hospitals today provide care to patients across a connected continuum of care, geared toward managing the health of a population in addition to individual patients.

a. Would limiting patient eligibility to uninsured patients or patients of a certain income level be an appropriate program change?

We do not think that limiting patient eligibility would be an appropriate program change. The value of the 340B program to Mission Health in FY 2017 was approximately $40 million. Our FY 2017 operating margin, inclusive of 340B savings, was $56 million. Self-pay patients are approximately 8% of our patient population. Therefore, limiting 340B use to uninsured patients would drop 340B savings from $40 million to roughly $3.2 million per year. Meanwhile, our charity care (at cost) plus bad debt would remain at $80 million per year, with community benefit for FY 2016 totaling over $183 million. This policy would clearly punish the very safety net hospitals that are charged with and are serving on the front lines to provide care to those who are not able to afford or access care, to fight the opioid battle, and to help solve the behavioral health crisis—without regard to the overall community benefits they drive and provide to their communities.

Increasingly, “bare bones” insurance policies are being offered to make insurance premiums “more affordable.” The hope is that family members will never have a serious and costly disease. However, when they do, insurance coverage with high deductibles and co-payments pushes important medical care and medications out of reach for many – or even most - middle class families. Proposed changes in the Affordable Care Act will likely exacerbate the problem as coverage mandates are reduced or eliminated to achieve “premium affordability.” These increasingly common situations provide the illusion of an “insured patient” while the patient is effectively uninsured for the bulk of his/her care.

In addition, the cost of important new drugs is defined largely by what the market will bear for the innovation delivered. A vital $100,000 drug would likely be completely inaccessible to a patient in a household with even an $85,000 in annual income; 20% coinsurance for this same “insured patient” would likely be out of reach. Even so, the patient’s insurance status and/or income level could preclude participation in the 340B program if we adopted program eligibility based on insurance and/or income level.

Health systems like Mission with 340B drug access play a vital role in this equation, as evidenced by the discussion at the hearing related to private practice versus hospital-based oncology practices. Mission oncology services provide a robust assistance program based on income, with patients up to 200% of federal poverty guidelines receiving free care, and a sliding scale payment system for households 200% to 300% of the federal poverty guidelines.

Mission supports reporting transparency for 340B savings and community benefit, and believes that, once reporting transparency is achieved, data collected can be used to support sound 340B policy discussion and decision-making.

8. During the hearing, you stated that contract pharmacies are "viewed as an extension of our own work." Do you believe all covered entities can make this statement, given the incredibly broad contract pharmacy arrangements managed by some hospitals and the significant distance between the hospital and contract pharmacy?

We can't speak specifically to other health system's pharmacy arrangements, but we would assume it is reasonably likely to be similar. Mission's contract pharmacies are "an extension of our own work" for two important reasons. First, the nexus/episode of care that identified the need for pharmaceuticals occurred at Mission Health. These are Mission Health patients. Second, margins derived by Mission from a contract pharmacy relationship inure to the 340B hospitals and their programming and support the robust and transparent community benefit program we have described, targeted to the specific needs of the people of western North Carolina.

With regard to "broad contract pharmacy arrangements", the pharmaceutical supply chain and how patients receive medications are evolving quickly and create oddities in 340B reporting. For example, while the corner drug store still exists, that corner drug store may be supported by a highly automated, centralized prescription processing facility or warehouse located hundreds of miles away from the hospital or pharmacy. The centralized facility ships medications to the local store every night. That warehouse facility, in order to be eligible for 340B drug shipments on behalf of the corner drug store, has to be listed today as a "contract pharmacy." The process reduces labor and distribution costs, but adds complexity to the supply chain, as well as the Mission 340B HRSA directory. In addition, specialty drugs are very expensive. Due to cost and labeler restrictions, the corner drug store is unable to stock these medications, forcing distribution into overnight mail order Specialty Pharmacies. Suddenly, the Specialty Pharmacy in Las Vegas is highly relevant to the care of patients in rural western North Carolina. To resupply that Specialty Pharmacy, Las Vegas has to be listed as a contract pharmacy for Mission. This dynamic has greatly increased the number of Specialty Pharmacies listed in our HRSA directory over the past six months. These situations are also likely applicable to other covered entities.

9. You stated during the hearing that several of your contract pharmacies are mail order or specialty pharmacies, which "haven't had a dollars' worth of revenue." Can you explain why this is the case, considering that contract pharmacies typically receive a dispensing fee for their services?

By way of background, Mission's agreements with its community pharmacy partners, including mail order, are based on a fixed dispensing fee model (i.e., we pay a fixed fee per prescription rather than using "revenue-sharing" models). Mission has made the very conscious decision to avoid "profit sharing" models with our contract pharmacies.

When Mission made the decision to add Specialty Pharmacies to our Contract Pharmacy network, the result was that we would be adding 16 new Contract Pharmacy locations, even though we had only signed two new Contract Pharmacy agreements. The reason for this is that each vendor has multiple mail order locations which could potentially provide mail order Specialty Pharmacy services for our patients. **As of October 2017, these sixteen Specialty Pharmacy locations have yet to provide a single qualified 340B prescription**. Specialty medications tend to be low in volume, but high in cost. Therefore, it is not surprising that we would have these contracts in place since July 1, 2017, yet have no qualified prescriptions, and therefore $0 revenue for Mission or our vendors as a result of these agreements. An additional 10 of our Contract Pharmacies are warehouse/distribution facilities for our Contract Pharmacy partners. **They exist as "Contract Pharmacies" simply to allow for the shipment of bulk pharmaceuticals to a local drug store**. As such, we have not realized any revenue for Mission or these 10 "contract pharmacies" listed in the HRSA Directory for Mission.

Both of these are examples of drivers of the increase in the number of Contract Pharmacies listed in the HRSA 340B Directory and is visible to those studying this metric. Even so, using actual data for Mission Health and despite the increase in the number of contract pharmacies, we have relatively flat or declining contract pharmacy value over the last 4 years. The chart below provides our year-to-year contract pharmacy financials.