April 19, 2020

Honorable Xavier Becerra
Secretary
U.S. Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Becerra,

Congratulations on your appointment to lead the Department of Health and Human Services (HHS). We wanted to take this opportunity to thank you for your longstanding support of the 340B Drug Pricing Program (340B program) administered by the Health Resources and Services Administration (HRSA). As hospitals systems across the country with facilities enrolled as 340B entities, we look forward to working with you to maintain the sustainability of the program for entities such as ourselves.

The 340B program was created in 1992 to "permit covered entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." Our hospitals do just that by integrating our savings back into our communities through services and programs within and outside our physical walls in both rural and urban areas.

It is important to stabilize this program for the long-term. Therefore, we ask that you consider the following as you look to improve the program:

1. HHS should pay all hospitals the same rate for drugs dispensed, regardless of the type of hospital, including those participating in the 340B program and overturn the cuts under the outpatient prospective payment system (OPPS). We ask that HHS not discriminate, through lower payments, against any hospital, regardless of its designation or participation in the 340B program. Otherwise, the intent of the 340B program to provide support to safety net hospitals is not satisfied. **Please eliminate the unfair cuts to 340B hospitals under the OPPS.**
2. Recent actions by major drug manufacturers that restrict 340B pricing based on where we choose to have drugs shipped and dispensed has led to a negative impact on our health systems. During a public health emergency, any unfair practices have a direct impact on our communities. Now more than ever it is vital to protect the 340B program to maintain the best possible care for our patients. **HHS must require pharmaceutical manufacturers participate with contract pharmacies to abide by requirements under the 340B program.**
3. Late last year, HRSA implemented the 340B Administrative Dispute Resolution (ADR) allowing covered entities the means to appeal certain program violations found during a routine audit prior to removal from the program. Such a process is

commonplace for health care providers within other government programs, such as the avenue for appeals from the Centers for Medicare Medicaid Services (CMS) audits with the Provider Reimbursement Review Board (PRRB). This same type of process should be included in the 340B program. The Patient Protection and Affordable Care Act, signed into law on March 23, 2010, mandated that the Secretary promulgate regulations within 180 days to establish and implement an administrative process for the resolution of claims to protect both covered entities and manufacturers. Ten years later, there HRSA finally put this mechanism in place. **We request that HRSA continue to implement the ADR process to allow covered entities the ability to appeal judgements against them.**

4. When a covered entity is audited by HRSA, the results of the audit are posted on a public database. Any issues of non-compliance must be posted separately in a public address letter as a public notice to manufacturers. When manufacturers are audited – their results are kept confidential, and the outcomes of those audits are not posted on any HRSA public database. **We believe, in the spirit of transparency, that both covered entities and manufacturers should have their audit results equally accessible via public databases.**
5. HHS should create a repository for all necessary Medicaid Health Plans (both Fee-For-Service and Managed Care) containing each participating plan's prescription plan information, which is vital to maintain compliance with Medicaid Duplicate Discounts and improve program integrity across all 340B covered entities. The prescription benefit information should also include a standard methodology to allow Medicaid agencies to enter into a shared savings model with Covered entities as current Medicaid payment models often lead to overall increases cost to both Medicaid Agencies and 340B Covered Entities. **HHS should make a repository available for covered entities to ensure that they avoid Medicaid Duplicate Discounts.**
6. HHS should review rebates through pharmacy benefit managers (PBMs) and how the rebate program structure incentivizes PBMs to siphon off the benefits of the 340B program for themselves. PBMs have begun implementing policies to determine the savings that covered entities receive from 340B drugs in order to lower payments to covered entities. **HHS should review PBM rebate programs, and any payment changes for 340B covered entities.**
7. Certain PBMs have created new ways to distribute high-cost infusion drugs as a way to circumvent the 340B pricing requirements. Infusion drugs, including those for cancer, are now required to be purchased through the PBM preferred pharmacy and sent either to the hospital or directly to the patients home then brought to the infusion center for administration. Dangerous and hazardous drugs are sent through the mail system and are subject to uncontrolled temperatures which could lead to stability issues. Patients experience financial hardship paying for the upfront cost of their medication at the point of sale instead of after infusion is administered through the provider payment. Excess waste of medication occurs as dosage adjustments (over

and under dosage changes) occur on day of infusion administration and delays occur while medication is waiting to be received since it being sent through the mail instead of the normal drug supply chain. **Highly sensitive infusion drugs should remain in the normal supply chain and not be allowed to be distributed directly to the patient.**

8. HHS should not allow manufacturers to turn the 340B program from an upfront discount program to a back-end rebate program as has been proposed by some outside information technologies sources. If this type of model were to move forward without HHS intervention, it would be both financially (significantly increasing upfront costs for covered entities) and administratively (uploading thousands of claims and monitoring for rebates) burdensome for 340B hospitals. **HHS must intervene and halt any movement by manufacturers to turn the 340B program into a rebate model.**

We appreciate the opportunity to work with the Department on this essential lifeline for our hospitals and the patients we serve. If you would like to discuss any of these comments or recommendations in more detail, or if we can provide you with additional information, please do not hesitate to contact Devon Seibert-Bailey at Strategic Health Care at 202-266-2600 on our behalf.

Thank you for your support of the 340B Drug Pricing Program.

Sincerely,

Aultman Health Foundation
Ohio

Baptist Health
Kentucky and Indiana

CentraCare
Minnesota

Centura Health
Colorado and Kansas

Hackensack Meridian Health
New Jersey

Henry Ford Health System
Michigan

Legacy Health
Oregon and Washington

MaineHealth
Maine and New Hampshire

Methodist Le Bonheur Healthcare
Tennessee and Mississippi

Monument Health
South Dakota

Mountain Health Network
West Virginia

Munson Healthcare
Michigan

Nebraska Medicine
Nebraska

OSF Health Care
Illinois and Michigan

Parkview Health
Indiana and Ohio

Piedmont Healthcare
Georgia

Presbyterian Healthcare Services
New Mexico

ProMedica
Ohio and Michigan

The Queen's Health Systems
Hawaii

Sanford Health
South Dakota

SCL Health
Colorado, Montana, and Kansas

St. Luke's Health System
Idaho

University of Utah Health
Utah

University of Vermont Health Network
Vermont

cc: Diana Espinosa, Acting Administrator, Health Resources and Services Administration
Elizabeth Richter, Acting Administrator, Centers for Medicare and Medicaid Services
Chair and Ranking Member, Senate Health, Education, Labor, and Pensions Committee
Chair and Ranking Member, House Energy and Commerce Committee