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Krista Pedley, PharmD, MS
Director, Office of Pharmacy Affairs
Health Resources and Services Administration
Fishers Lane, Mail Stop 08W05A
Rockville, Maryland 20857

Re: RIN 0906-AB08

Dear Captain Pedley,

On behalf of the Temple University Health System (TUHS) and its physician-affiliated companies, comprised of the Lewis Katz School of Medicine at Temple University (TU-LKSOM), Fox Chase Cancer Center Medical Group, Inc. (Fox Chase) and Temple Physicians, Inc. (collectively referred to as Temple), I thank you for the opportunity to submit the following comments in response to the Health Resources and Services Administration's (HRSA) proposed rule entitled, *340B Drug Pricing Program Omnibus Guidance* (Guidance).

We are extremely concerned that the Guidance's new definition of "patient", if implemented as proposed, would significantly impede our ability to continue as a major point of access for the medical services we now provide to our low-income patients. Thus, we respectfully request that the final Guidance address our concerns and suggestions regarding patient definition.

We explain these concerns more fully below. In the meantime, we provide a brief overview of Temple University's academic healthcare enterprise and our unique public service mission.

Background on Temple:

TUHS is an academic health system dedicated to providing access to quality patient care and supporting excellence in medical education and research. As the academic teaching hospital of Temple, Temple University Hospital (TUH) is a 714-bed non-profit acute care hospital that provides a comprehensive array of medical services to its low-income communities, and a broad spectrum of secondary, tertiary and quaternary care to the Greater Philadelphia area. In addition to its main campus in North Philadelphia, TUH includes its Episcopal and Northeastern campuses, both of which are located in economically distressed areas within 3 miles of the TUH main campus. TUHS also includes Fox Chase Cancer Center, an NCI-designated comprehensive cancer center; Jeanes Hospital, a community hospital in lower Northeast Philadelphia; the Temple Transport Team, a ground and air-ambulance company; and Temple Physicians, Inc., a network of community-based specialty and primary-care physician practices.

Temple's nationally-renowned physicians offer dozens of powerful new options for patients who, just a few years ago, were considered untreatable. Using sophisticated technologies and personalized treatments, Temple physicians are working to alter the course of serious disease. And in over a dozen research centers at

TU-LKSOM and Fox Chase Cancer Center, our faculty are speeding the transformation of fundamental scientific discoveries into practical therapies that may one day dramatically improve human health.

As our chief clinical teaching site, TUH is staffed by 400 physicians of TU-LKSOM's faculty practice plan known as Temple University Physicians (TUP), an unincorporated division of Temple University – Of The Commonwealth System of Higher Education, as well as the physician scientists from Fox Chase and Temple Physicians, Inc. Temple Physicians represent 17 academic departments including subspecialties in emergency medicine, family practice, pediatrics, cardiology, gastroenterology, oncology, obstetrics and gynecology, orthopedics, neurosurgery, neurology, general and specialty surgery and psychiatry. Temple physicians also staff important clinics that address major public health concerns such as the Comprehensive NeuroAids Center at Temple University, which is dedicated to improving the public health impact of bench-to-clinic research associated with HIV-induced neurological diseases and cognitive disorders.

The structure of Temple University's academic health enterprise, including a symbiotic relationship between its major teaching hospital and faculty practice plan, including financial support from TUH for the clinical operations of TUP, is typical of the organization of many academic medical centers across the United States. Like many other academic medical centers, Temple University is the corporate parent of TUHS, which in turn, is the corporate parent of TUH. As noted above, TUP and the TU-LKSOM are divisions of Temple University. TUP, together with Fox Chase and Temple Physicians, Inc., are responsible for delivering quality medical care for patients in the hospital inpatient and outpatient setting, as well as in Temple ambulatory care settings.

While Temple's healthcare enterprise is not unique in terms of its structure, it is unique in terms of the extraordinarily vulnerable patient population we serve. TUH serves one of our nation's most economically challenged and diverse urban populations. It is an indispensable provider of care in the largest city in America without a public hospital. Within its primary service area, 35% of area residents live below the federal poverty level (more than twice the national average) and the unemployment rate is approximately 20%. About 47% of individuals living in the community identify as Black-non Hispanic, and about 24% as Hispanic. TUH is located in a federally designated Medically Underserved Area, and our Episcopal Campus is located in a federal Empowerment Zone.

About 84% of our inpatients are covered by government programs: 33% by Medicare and 51% by Medicaid. Patients dually eligible for both Medicare and Medicaid comprise about 20% of our total inpatient population. TUH serves as a critical access point for vital health services. Last year we handled more than 130,000 patients in our emergency department; 11,000 patients in our psychiatric crisis response center; 2,100 discharges from our inpatient Behavioral Health unit; 700 victims of gun and stab violence in our Trauma unit, the highest number in Pennsylvania, and more than 300 patients in our Burn Center. We delivered about 3,100 babies, of whom 90% were covered by Medicaid.

Last year, TUH provided \$ 47 million in free and under-reimbursed care to our indigent patient population we serve. All TUP physicians care for patients of TUH, including those covered by Medicaid, in the inpatient, outpatient and ambulatory settings.

TUH is the sole participating covered entity within TUHS, and maintains child sites in the 340B program. Each of these sites is well recognized for the vital medical services and for the access to those services offered to the low-income patients they serve.

TUH is exactly the type of essential hospital the Congress intended to shield from escalating drug prices in 1992 when the 340B program was enacted. However, the new definition of "patient" proposed in the Guidance would eliminate all of our savings from the 340B program. This would have a devastating effect on TUH and on the communities it serves, erasing a razor-thin operating margin and threatening its ability to provide the many of the vital services now provided by Pennsylvania's largest safety net hospital.

General Concerns with Patient Definition: Under the 340B statute, subsection (a)(5)(B) states as follows:

PROHIBITING RESALE OF DRUGS.-With respect to any outpatient drug that is subject to an agreement under this subsection, a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity. (Emphasis added)

Although the statute specifically defines numerous terms, it is notable that the statute does not define the term “patient”. Webster’s Collegiate Dictionary defines “patient” as “an individual waiting or under medical care or treatment”. It is significant that the heading of the above subparagraph is “PROHIBITING RESALE OF DRUGS” to non-patients. Clearly, Congress intended that the covered entity utilize the benefit of the 340B discount for actual patients for whom the entity is providing care, and not to extend the benefit to consumers who obtain drugs through a means that allows them to bypass medical care, such as through a mail order pharmacy. It is also notable that Congress did not otherwise limit the term “patient”.

In its Guidance, HRSA proposes “a clarified definition of patient for purposes of the 340B program”. In so doing, HRSA dramatically deviates from the intent of Congress and the plain language of the statute without legislative authority to do so. The definition defies the common usage of the term “patient” and is divorced from the reality of how care is delivered in academic medical centers like Temple. The proposed definition would drastically limit, if not eliminate in its entirety, the use of 340B pricing for individuals who are legitimate patients of Temple for other purposes such as receiving reimbursement, EMTALA and medical liability. It makes poor policy sense to treat the same individual as a patient for some purposes and not for 340B. Further, it contracts the scope of the 340B program and harms the very safety-net institutions caring for vulnerable citizens that it was designed to shield from astronomical drug prices.

The new patient definition is neither clarifying nor interpretive, nor is it persuasive; it is substantively and dramatically narrowing the scope of the 340B program well beyond Congressional intent. Congress did not indicate in the statute that the scope of the discount had to be limited to each and every prescription; just that the individual receiving the drug purchased at a 340B price is actually a patient. Being a patient of a covered entity means that there is a patient-provider relationship such that the individual is receiving health care services from the covered entity. It is not reasonable for HRSA to extrapolate from a statutory prohibition on reselling drugs to non-patients that the covered entity must demonstrate that each and every prescription or order results from a particular health care service provided on a particular day. Such an approach not only defies common sense and the effective practice of medicine, it is completely contrary to HRSA’s goals of improving access to healthcare services for vulnerable populations.

Patients see multiple providers for multiple reasons, and their medical needs are often provided by more than one provider. A patient with comorbidities may visit multiple clinics over a period of time or in a single episode. Regardless of the course of treatment, there is an established patient-provider relationship and any medical professional who delivers treatment bears some responsibility for the patient’s care. Similarly, a patient who is not routinely sick may visit his/her primary care provider at the academic medical center and receive refill prescriptions from time to time. The fact that a person obtains a prescription refill does not negate his or her status as a “patient.” By limiting a 340B priced drug only to those that “result” from a health care service on a particular day, the Guidance incentivizes unnecessary health care utilization and clinic visits and drives up the cost of care.

Specific Concerns with Patient Definition Elements:

1) The first element requires that an individual receive a health care service at a covered entity site which is registered in the 340B program and is listed on the public 340B database. The requirement that an individual receive a health care service at a registered site is problematic for Temple for several reasons:

- a. This requirement ignores the complex inter-relationships between how care is provided among hospitals and their affiliated physicians in academic medical centers. This element would exclude 340B pricing for prescriptions written by affiliated physicians in faculty based physician practices, either for primary, specialty or follow up care. For example, a TUP physician might prescribe medications at a TUP practice as a follow-up to an outpatient service provided at TUH, or, a TUP physician might prescribe a service to be performed at the hospital outpatient department. In each case, the TUP practice is not a TUH offsite clinic that appears on the Medicare cost report, although in each case, TUH provides a service to, and does maintain a medical record of, the patient, demonstrating shared responsibility for care of the patient. Both TUH and its affiliated physician companies have access to each other's medical records as needed for patient care.
- b. In structuring TUH outpatient care delivery services years ago, TUHS concluded that care could be delivered more effectively and efficiently in a physician office rather than as a hospital outpatient department. To meet the first element, Temple would have to restructure its physician practices to become hospital outpatient departments. This structural change would be enormously expensive, burdensome and complex. For example, TUH would be required to pay or provide some other consideration to contract with its affiliated physician companies for physician services provided to hospital based clinics, as opposed to the current practice of Temple physicians seeing patients in their offices. Further, it would unnecessarily increase the cost to our patients and the Medicare program as they would now be considered hospital "outpatients", requiring higher patient copays, deductibles and additional facility fee reimbursements. Forcing covered entity hospitals that are already struggling to serve their low-income patients to restructure their entire outpatient delivery system for the purpose of being able to preserve desperately needed savings through 340B cannot be what HRSA intended. Congress most certainly did not intend to increase the cost of health care to low income patients, or to the Medicare program, when it enacted 340B legislation.
- c. Requiring that the individual receive a health care service each and every time a prescription or order is filled incentivizes unnecessary utilization of health care services. Patients do not always require a face-to-face health care service; sometimes all they need is to talk to their provider who will then prescribe a new prescription or simply a refill. Requiring a health care service drives up the cost of health care at the same time the federal government and private insurers are providing countervailing pressure to streamline care and reduce unnecessary health care services and utilization. Temple has strived to provide access to care for many needy individuals through the most cost-effective means possible through our physician offices. This requirement contravenes our efforts to streamline care and improve patient access.

The implications of this requirement are substantial. First, it requires that all follow-up care be done by outpatient departments of the hospital, reducing TUH's savings under the 340B program by as much as ninety percent. Furthermore, it would force a shift to hospital outpatient departments to provide follow-up care, increasing costs to TUH, patients and the Medicare program alike. In addition, TUH would be financially penalized by other payors that refuse to pay the higher cost of a hospital based clinic when the service could be billed as a physician visit under evaluation and management codes. This requirement should be stricken. In the alternative, Temple suggests that academic medical center physician practice locations be deemed to meet the requirements of this first element.

- 2) ***The second element requires that the health care service be delivered by a health care provider either employed by the covered entity or who is an independent contractor such that the covered entity may bill for the professional services of that provider.*** With respect to the issue of the billing entity, there is simply too much ambiguity in the Proposed Guidance regarding the term "may bill" to

know what HRSA intended. Even if HRSA clarifies this element, we suggest an additional comment period to allow covered entities a meaningful opportunity to comment.

Notwithstanding the foregoing, this requirement fails to recognize the nature of hospital-physician relationships in academic medical centers. TUH does not employ its affiliated physicians, nor does it contract for their services to patients in the hospital through a personal services agreement, however TUH depends upon those physicians to provide care to their patients. Further, TUH does not bill for the professional services provided by those physicians. The ability of a hospital to bill for a service provided by a physician has no bearing on whether an individual is a patient of the hospital. Such billing arrangements are dictated by numerous other factors, including state law and payor requirements.

For example, hospitals routinely contract with emergency physician groups to provide care to patients in their emergency departments but do not assume billing rights for the professional fees of such physicians who prefer to bill for their own services while the hospital bills for the facility fee. That the hospital has not assumed the right to bill for the physician's professional fees in addition to the hospital's facility fee does not mean that the individual being treated by the physician in the hospital emergency department is not a patient. They are a patient for all other purposes – such as EMTALA and medical liability. Yet under HRSA's new patient definition in this example, the individual would not be considered a patient for 340B purposes. We are at a loss to understand how a patient can be treated in the emergency department of a 340B eligible hospital and not be considered a patient simply because the physician chooses to bill for his or her own professional services. This limitation goes far beyond the plain meaning of "patient" as provided in the statute.

The guidance summary states that faculty practice arrangements and established residency and internship programs are examples of covered entity-provider relationships that would meet element two of the patient definition test. We appreciate HRSA's recognition of the unique nature and relationship between faculty group practice plans and residency programs as part of academic medical centers. Nevertheless, the Guidance also states that simply having privileges or credentials at a covered entity is not sufficient to demonstrate that an individual treated by that privileged provider is a patient of the covered entity for 340B program purposes. While we appreciate HRSA's recognition in the summary of the unique nature of faculty arrangements, that language is insufficient to shelter Temple because its affiliated physicians, while under common control, are neither employed nor under contract such that TUH may bill for the physician professional fees. Temple physicians bill for their own professional fees; it is not possible under our current arrangements for TUH to bill for physician services.

As discussed below, we believe that if HRSA does not withdraw the proposed definition of "patient", then HRSA should more clearly recognize individuals receiving care as part of an academic medical center as patients for 340B purposes, regardless of specific employment or billing relationships and geographic location. Failure to do so will not only significantly adversely affect the ability of TUH to provide vital services to its vulnerable community, but also disrupt the long-standing inter-relationships designed to further the academic, research and patient care mission of the academic medical center.

Temple does not support a narrowing of the term "patient" beyond that which was intended by Congress in drafting the statute such that the covered entity provides health care services to an individual. Likewise, we cannot support HRSA's proposal to link patient status to a provider's ability to bill for a particular service. Thus, we urge HRSA to strike the second element as well. However, should HRSA choose to include a more narrow interpretation of "patient" in the final Guidance, we urge HRSA to develop a more meaningful definition that recognizes academic medical center inter-relationships in the provision of care beyond physician-hospital privileges. Such recognition of academic medical

center/affiliated physician practice arrangements should be included in the substantive text of the Guidance as well as in the summary.

3) *The third element requires that the individual receives a drug that is specifically ordered or prescribed by that health care provider as a result of the health care service in element (2)*

- a. This requirement that the prescription or order must “result” from the health care service adds extraordinary complexity by tying each and every prescription or order to a particular health care service provided on a particular date. As noted above, this requirement unnecessarily increases health care costs and is contrary to an efficient and effective health care delivery system. Further, it will be very challenging to comply with and document that a prescription is a direct result of a specific health care service, yet failure to do so would eliminate the ability to use 340B pricing when patients do not need a physician visit. HRSA has no statutory basis for limiting the use of 340B to a specific health care service on a particular date related to a particular drug. The statute simply says the covered entity cannot resell or otherwise transfer the drug to a non-patient; it did not otherwise limit the term to a specific, time, date and place.
- b. As a further example, and as an academic medical center, Temple provides tertiary and quaternary care to patients with very complex medical conditions and comorbidities. These patients require ongoing care and monitoring. When patients are being seen and cared for by Temple physicians and receive services at the covered entity, they should be eligible for 340B priced drugs, even if the hospital services are not a direct result of a physician visit and tied to the specific service rendered. A patient's care and treatment for ongoing disease is not rendered in separate and distinct boxes. The requirement should be stricken as it is well outside of the common sense meaning of the term “patient” and beyond HRSA’s authority.

4) *The fifth element requires that the drug is ordered or prescribed pursuant to a health care service that is outpatient.* The result of this dramatic change to the 340B program is to prohibit hospitals from utilizing 340B priced provided to patients being discharged from the hospital and to be self-administered in an outpatient setting. Since the inception of the 340B program, hospitals have utilized discharge prescriptions to provide low-income and other patients with the drugs they will immediately need upon going home to recover, continue their treatment and avoid a readmission. HRSA has incorrectly and impermissibly excluded the provision of covered outpatient drugs to their patients. The statute doesn’t prohibit the provision of covered outpatient drugs to individuals who have been inpatients, but rather to non-patients where there is no provider-patient relationship. An inpatient is a patient reflecting a provider-patient relationship. There is nothing in the statute allowing HRSA to prohibit 340B pricing for individuals who are being discharged and who will utilize the covered outpatient drug at home or in another outpatient setting as long as the definition of covered outpatient drug is met.

TUH currently provides covered outpatient drugs to patients leaving the hospital to be administered as outpatients. We know that providing access to medications where and when they are needed is the most effective means of producing the best patient outcomes and preventing unnecessary utilization of health care resources, such as a preventable readmission. This requirement is completely contrary to all our efforts to promote population health and prevent readmissions of indigent and vulnerable patient populations who may otherwise have no access to drugs that could prevent their readmission. It is also contrary to the entire drive by CMS and the Congress to improve service delivery and improve continuity of care. It will create an obstacle to streamlined services and result in increased costs and avoidable utilization of health care services.

Temple is also concerned about the impact and complexity of subsequent payor determinations, such as when a patient was billed as an outpatient but is later determined to be an inpatient. This

confusion can be eliminated simply by eliminating this unnecessary requirement that has no basis in statute. This element of the patient definition has no statutory foundation and should be stricken.

- 5) ***The sixth element requires that the patient records are accessible to the covered entity and demonstrate that the covered entity is responsible for the care.*** We agree that maintenance of records is indicative of a patient-provider relationship and evidences shared responsibility for the patient's health care. However, responsibility for care isn't mutually exclusive such that only a covered entity provides all of the patient's care. That is simply not the world of health care delivery. Many patients receive care from multiple providers for multiple conditions or comorbidities. The 340B statute does not require that a patient only receive care from the covered entity; it's only limitation is that the individual is a patient, meaning that the individual is receiving some health care services from the covered entity. The HRSA guidance should not require, explicitly or implicitly, that the individual needs to be receiving all of his or her care from the covered entity.

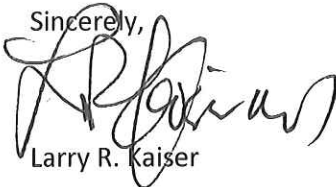
In summary, Temple urges HRSA to withdraw the proposed patient definition. HRSA has not been authorized by the Congress to define "patient" in a way that narrows the scope of the 340B program. As proposed, the patient definition strips the entire benefit of the 340B program away from TUH, harming the vulnerable communities we serve, increasing costs to patients and federal health care programs, and directly contravenes the intent of Congress in ensuring savings from high drug prices for essential hospitals and other safety-net providers.

If HRSA does not withdraw the definition, at a minimum, HRSA should exempt academic medical center covered entities such as TUH from the patient definition.

HRSA should allow the President or CEO of a covered entity that is part of an academic medical center to certify that the covered entity's 340B activities are limited to individuals for whom the covered entity maintains a medical record and provides care in conjunction with its affiliated physician companies.

Thank you for the opportunity to comment on this important issue. Should you have any questions or wish additional information, feel free to call me directly or contact Katherine Levins at 215-707-4851 or Katherine.Levins@tuhs.temple.edu.

Sincerely,



Larry R. Kaiser