MISSOURI HOSPITAL ASSOCIATION

Missouri Primary Care Association

September 4, 2020

Thomas Engels, Administrator
Health Resources and Services Administration
5600 Fischers Lane
Rockville, MD 20857

Dear Administrator Engels:

You are aware of concerns and objections regarding the efforts of a number of pharmaceutical manufacturers to limit the breadth of the 340B drug discount program. The Missouri Hospital Association and the Missouri Primary Health Care Association resoundingly reiterate those concerns and objections. The diverse but well-choreographed efforts by these pharmaceutical manufacturers upend long-standing 340B practices in order to trim their financial obligations. We believe those efforts are illicit and unjustified. We ask your agency to act quickly and decisively to block them and maintain the integrity and intent of the 340B program.

These pharmaceutical manufacturers are unilaterally creating new obstacles to the use of 340B drug discounts to benefit low-income patients. Some rely on onerous new demands for data and documentation couched as criteria for payment. Others arbitrarily declare that drug discounts will no longer be provided through contract pharmacies, brazenly attempting to negate by fiat a well-established component of the 340B program.

These pharmaceutical company forays take different approaches, but they all run counter to both the letter and spirit of the 340B law. There have been questions raised over the years about the parameters of HRSA's regulatory authority over 340B. After debating expansions of that authority, key Congress committees have urged HRSA to make full use of the regulatory authority it already has. To that end, our organizations implore HRSA to do what it can and must do to stifle these attempts to undermine the 340B program. Low-income patients are being deprived of the benefit of 340B drug discounts to which they and the qualified safety net providers who serve them are entitled by law and long-standing practice.

On September 3, the chairpersons of the House of Representatives Energy and Commerce Committee and its subcommittees on Health and Oversight and Investigations wrote Secretary Azar regarding this matter. We concur with the sentiments expressed as to HRSA's capacity and responsibility to act.

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HHS has an obligation to ensure manufacturers comply with the law. Furthermore, Congress has provided you with tools, including manufacturer auditing rights and civil monetary penalties, to enforce it. Failure to enforce 340B requirements threatens to undermine program integrity. Allowing manufacturers to institute extralegal requirements on covered entities under the threat of refusing to ship drugs as required, or allowing manufacturers to pick and choose where they will comply with program requirements, could set us on a treacherous path where program participants might disregard any or all of their legal obligations.

Thank you for your consideration of this vitally important matter.

Sincerely,

Herb B. Kuhn
President and CEO
Missouri Hospital Association

Joe Pierle
President and CEO
Missouri Primary Care Association

Hk:Jp/drd