

525 Clinton Street
Bow, NH 03304
Voice: 603-228-2830
Fax: 603-228-2464



61 Elm Street
Montpelier, VT 05602
Voice: 802-229-0002
Fax: 802-223-2336

September 20, 2017

Submitted electronically via <http://www.regulations.gov>

Captain Krista Pedley
Director
Office of Pharmacy Affairs
Healthcare Systems Bureau
Health Resources and Services Administration
5600 Fishers Lane
Mail Stop 08W05A
Rockville, MD 20857

Re: Comments on RIN 0906-AB11 -Proposal to Further Delay Effective Date of 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation until July 1, 2018

Dear Capt. Pedley:

Bi-State Primary Care Association appreciates the opportunity to comment on the Health Resources and Services Administration's (HRSA) solicitation for comments on further delaying the effective date of the Final Rule on 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties (CMPs).

Established in 1986, Bi-State is a nonpartisan, nonprofit 501(c)(3) charitable organization that promotes access to effective and affordable primary care and preventive services for all, with special emphasis on underserved populations in Vermont and New Hampshire. Bi-State's combined Vermont and New Hampshire membership includes 22 Federally Qualified Health Centers delivering primary care at over 80 sites and serving over 236,000 people. The 340B program plays a critical role in enabling our members to achieve their mission of providing affordable comprehensive primary and preventive care because the health centers are able to reinvest their 340B savings into activities that advance that mission.

Accordingly, Bi-State is writing to express our support for the comments submitted by the National Association of Community Health Centers (NACHC.) Like NACHC, we oppose the most recent proposal to delay the effective date for the Final Regulation around CMPs and Ceiling Price Calculations, this time until July 1, 2018, for the following reasons:

1. Drug manufacturers currently operate largely under an "Honor System" when it comes to charging 340B providers the appropriate ceiling price. Extensive data demonstrates that

525 Clinton Street
Bow, NH 03304
Voice: 603-228-2830
Fax: 603-228-2464



61 Elm Street
Montpelier, VT 05602
Voice: 802-229-0002
Fax: 802-223-2336

the Honor System is not working, as covered entities – particularly smaller ones – are frequently overcharged by drug manufacturers for drugs purchased under 340B.

2. Currently covered entities have no ability to sue manufacturers over 340B overcharges; rather HRSA has the ability to enforce 340B pricing requirements through CMPs. HRSA's language in the Federal Register indicates that the agency is aware that some manufacturers are still out of compliance with ceiling price requirements.
3. The factors listed in points 1 and 2 above highlight the need for the Final Rule to go into effect immediately, so statutory requirements that have been in effect for 25 years can be enforced.

In closing, Bi-State appreciates the opportunity to submit comments on this important issue, and both our staff and member FQHCs and Rural Health Clinics would be happy to provide further information that would be helpful. Bi-State strongly urges HRSA to implement this Final Rule immediately, and not to delay it until July 1, 2018. Please do not hesitate to contact me at (603) 228-2830 extension 112 or via email at tkuenning@bistatepca.org if you would like additional information or require clarification on the comments presented above.

Sincerely,

Tess Stack Kuenning, CNS, MS, RN
President and Chief Executive Officer
Bi-State Primary Care Association