

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

December 4, 2020

The Hon. Alex Azar, Secretary
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Re: RIN 0991–AC24 Securing Updated and Necessary Statutory Evaluations Timely

Dear Secretary Azar:

Bi-State Primary Care Association (Bi-State) appreciates the opportunity to provide input on the Proposed Rule: Securing Updated and Necessary Statutory Evaluations Timely.” In general, Bi-State welcomes and encourages measures which increase transparency and accountability and foster stakeholder engagement through public notice and comment. We do, however, have some concerns with this proposed rule as currently drafted. Given the importance of the Proposed Regulations Rule and the dire consequences if agencies fail to complete required reviews on a timely basis, Bi-State opposes the Proposed Regulations Rule until a detailed analysis of the potential consequences can be conducted, and urges HHS to withdraw it immediately.

Established in 1986, Bi-State is a nonpartisan, nonprofit 501(c)(3) charitable organization promoting 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 21 Federally Qualified Health Centers, one Look-Alike, one Rural Health Clinic, Planned Parenthood of Northern New England, Vermont Coalition of Clinics for the Uninsured, North Country Health Consortium, Community Health Access Network, and the Area Health Education Centers in both Vermont and New Hampshire.

Comment on the Proposed Regulations Rule

Bi-State strongly supports government accountability, including efforts to ensure that regulations governing health care providers generally, and the Health Center Program specifically, remain current and up-to-date. It is equally important that regulations strive for consistency in implementation without interruption that could adversely impact operations. Federal regulations provide quality, compliance, and policy guidance to ensure safe and effective delivery of care to our patients. Regulations play a significant role in how our

members provide services for their patients each day. Reliability and stability of operations are critical for ensuring that our vulnerable populations retain access to the services on which they rely and that are crucial to their health and welfare.

Regulations are critical in implementing government payer programs – including Medicaid, Medicare, and the Children’s Health Insurance Programs. These programs provide coverage for the majority of our patients in New Hampshire and Vermont and represent a principal source of health center revenues. Just as consistency of operations is critical for the health of our patients, revenue stability is essential for maintaining the strength of health center organizations. A strong regulatory framework provides all stakeholders – including states, provider organizations, managed care plans, patients – with both the clarity and constancy they need to operate on a day-to-day basis and the key guidance necessary to understand their various rights and obligations.

Bi-State concurs with the *overall goal* of the Proposed Regulations Rule and welcomes efforts to modernize and streamline the various regulatory approaches under which our members operate and are reimbursed. Done in a workable manner, this can reduce the administrative and economic burdens that impact our members’ ability to serve their patients and their communities. However, we do not believe the process proposed in this rule is workable.

Administrative burden to agencies

As crafted, the Proposed Regulations Rule would create a significant administrative burden on the agencies tasked with the required regulatory review. This would divert resources from critical ongoing work that includes efforts to address the COVID-19 pandemic. Both New Hampshire and Vermont are facing record COVID-19 surges at this time. Beyond the pandemic response, there are critical health issues that require attention including diabetes and hypertension. HHS’ estimate is that the proposed rule would cost nearly \$26 million dollars over ten (10) years and necessitate ninety (90) full-time staff positions to undertake the required reviews. Given these estimates, it is highly likely the Proposed Rule would adversely affect HHS’ ability to focus on managing the pandemic, administering current programs, issuing new regulations, and revising those existing regulations that require immediate modification or amendment.

Further, the establishment of a two (2) year deadline for the various agencies within HHS to review existing regulations that have been in place for more than ten (10) years is not feasible. Within the first two (2) years, HHS estimates the need to assess at least 12,400 regulations that are more than ten (10) years old. This review will require significant time and resources. Especially during crisis situations like COVID-19, it is critically important that HHS have the flexibility and bandwidth to focus and respond quickly to immediate needs.

From an operations perspective, implementation of the Proposed Regulations Rule would create legal uncertainty regarding the validity and enforceability of regulations throughout the review process. A substantial danger posed by the Proposed Regulations Rule is that important regulations may be arbitrarily rescinded because there are simply not enough HHS staff or resources to undertake such a sweeping review process. Regulations that do not complete the complicated and time-consuming review process would summarily expire, potentially leaving

vast, gaping holes in the regulatory framework that is critical for implementing important HHS programs and policies.

Such consequences would be devastating to health care providers like ours. This lack of consistency and stability, as discussed above, is crucial for our providers to appropriately serve the patients and communities who rely upon them. Effectively, the consequences would fall upon health centers, primary care practices, and communities that are not at fault, but nonetheless will suffer the most.

Conclusion

Bi-State strongly supports government accountability and welcomes any attempts to modernize, update, and streamline the regulatory approaches under which health care providers like our members operate in order to minimize the economic and administrative burdens that could adversely impact their ability to serve their patients.

However, for the reasons discussed above, we believe that the process outlined in the Proposed Regulations Rule is unworkable. The administrative burden placed on the various agencies to complete required reviews is substantial and the requirement to complete such reviews within a deadline of two (2) years is not feasible. Of even greater importance, the consequences for failure to complete the reviews within the required deadline could be devastating for our health centers, primary care practices, and patients.

Given the truncated 30-day comment period, Bi-State opposes the Proposed Regulations Rule until a detailed analysis of the potential consequences can be conducted and urges HHS to withdraw it immediately. Alternatively, if HHS decides to proceed with the promulgation of the Regulations Rule, Bi-State requests that HHS: (i) extend the two- (2) year review period for existing regulations to a period not less than five (5) years; and (ii) build in safeguards to ensure that regulations critical to the operation of safety net providers will not automatically rescind due to the failure of HHS or one of its agencies to complete a timely review. For purposes of the latter, Bi-State requests that HHS issue a second notice requesting appropriate stakeholder input.

Thank you for your consideration of these comments. Should you have any questions about these comments, please feel free to contact Georgia Maheras at gmaheras@bistatepca.org or 802-229-0002 ext. 218.

Sincerely,

Tess Kuennig

Tess Stack Kuennig, CNS, MS, RN
President and Chief Executive Officer