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May 5, 2015

Submitted via www.regulations.gov

James G. Touhey, Jr.
Director, Torts Branch, Civil Division
Department of Justice
Room 8098N
National Place Building
1331 Pennsylvania Avenue NW.
Washington, DC 20530

Re: Docket No. CIV 150: Determination That an Individual Shall Not Be Deemed an Employee of the Public Health Service

Dear Mr. Touhey,

Bi-State Primary Care Association is pleased to respond to the above-referenced Notice of Proposed Rulemaking (NPRM) published by the Department of Justice (DOJ) on March 6, 2015 (80 Fed. Reg. 12104).

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 works with federal, state and regional health policy organizations, foundations and payers to develop strategies, policies and programs that provide and support community-based primary health care services in medically-underserved areas. Our members include Community Health Centers, which include Federally Qualified Health Centers (hereafter interchangeably referred to as Health Centers or FQHCs); Rural Health Clinics; private and hospital-supported primary care practices; Community Action Programs; Health Care for the Homeless programs; Area Health Education Centers; Clinics for the Uninsured, and social service agencies.

The Health Centers in Vermont and New Hampshire participate in the Federal Tort Claims Act (FTCA) coverage for their patients. It is an extremely important and valuable federal program. The changes introduced by the DOJ through its proposed NPRM could significantly alter this program. As such, Bi-State is providing comments to your NPRM. In addition to our comments, we fully endorse the National Association of Community Health Center's letter that will be submitted before the deadline. Our letter parallels their comments and concerns.

Summary of Comments:

- A. Bi-State would like the DOJ to provide information on how it will operationalize each of the five statutory criteria used to determine if an individual poses an "unreasonably high degree of risk of loss" to the Government. Since the current NPRM provides no information in this area, and there are numerous issues to be addressed, we request that this part of the NPRM be re-issued for public comment once such information is provided.
- B. Bi-State recommends that DOJ expand the NPRM to discuss the nature of the consultation between DOJ and the Department of Health and Human Services, and permit public comment on these proposals.

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C. Bi-State recommends that individual providers who are subject to an administrative hearing be provided with an explanation of the reasons behind initiating official's determination at the time that he or she is notified of the hearing.

A. Determination of "Unreasonably High Degree of Risk of Loss"

Section 233(i)(1) of Title 42 grants the DOJ the authority to determine that an individual is not an employee of the Public Health Service (PHS) for purposes of FTCA coverage if doing so would "expose the Government to an unreasonably high degree of risk of loss." The provision goes on to list five criteria, any one of which could cause the Government to be exposed to an "unreasonably high degree of risk of loss."

The NPRM lists these five general criteria verbatim from the statute. However, it fails to provide any specific information on how DOJ will interpret and implement these criteria when considering whether a provider should be called for a hearing, or when evaluating a provider's records during the hearing process.

Bi-State recognizes that establishing strict definitions for each criteria (e.g., an exact number of claims which trigger a hearing) might limit DOJ's ability to react appropriately to variations across regions or areas of practice (e.g., OB versus internal medicine). However, the current NPRM goes to the other extreme by providing no guidance or clarification beyond the statutory language. This is problematic for several reasons, including:

- It will allow for significant variations in how the standards are interpreted, across regions, time, and DOJ officials.
- It permits DOJ to adopt interpretations which are significantly stricter than those applied by private providers of malpractice coverage, which we contend is counter to statutory intent.
- Providers will not know the standards against which they are being evaluated, making them unable to determine what they must do to comply with this regulation and avoid risking their status as a PHS employee. In addition, as discussed below, this will make it extremely difficult for them to prepare their defense when called to a hearing.

For these reasons, Bi-State requests that DOJ provide guidance on how it plans to interpret and operationalize each of the five criteria. Below, we give examples of areas where clarification would be helpful.

(1) *The individual does not comply with the policies and procedures that the entity has implemented pursuant to 42 U.S.C. 233(h)(1).*

- What evidence of compliance versus non-compliance will be considered?
- Are there certain policies and procedures that are afforded greater weight in making a determination?
- Could the determination be made on a single instance of non-compliance with a single policy or procedure by the individual or is a "pattern" of non-compliance required?

(2) *The individual has a history of claims filed against his or her as provided for under 42 U.S.C. 233 that is outside the norm for licensed or certified health care practitioners within the same specialty.*

- How will the "norm" be determined in order make a determination that the practitioner is outside of that norm? What data will be taken into consideration? Who has the expertise necessary to make such determinations? Will norms vary by specialty, or geographic area?
- Will the norm be presented as a single number or a range? Will any standard deviations be tolerated? Will it be based on the mean, median, or mode of claims filed against licensed or certified health care practitioners within the specialty?
- Will the individual(s) establishing the norm(s) use data that is publically available? If not, will it be made available? Will information as to the sources for the data be published?
- Will the equation used to determine the norm take into account the geographic area of practice or the practitioner's years of experience?

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- What constitutes the history of claims – is it over the practitioner’s years of employment, years of practice, or is there some other timeframe that will be established?
- How will the DOJ account for claims that were later determined to be frivolous or instances in which no judgment was awarded to the plaintiff (and therefore no loss to the Government)?

(3) *The individual refused to reasonably cooperate with the Attorney General in defending against any such claim.*

- How will “reasonably cooperate” be defined?
- Who will determine whether the individual refused to reasonably cooperate with the Attorney General?
- There could be instances in which the interests of the individual and the Attorney General may not be completely aligned – would the individual’s actions to protect his or her interest (whether or not on the advice of counsel) be considered to create an unreasonably high degree of risk of loss?

(4) *The individual provided false information relevant to the individual’s performance of his or her duties to the Secretary, the Attorney General, or an applicant for or recipient of funds under title 42, chapter 6A, United States Code.*

- What types of information is particularly relevant? Specific examples would be helpful.
- Will the timing of the discovery of false information be a factor in making the determination?

(5) *The individual was the subject of disciplinary action taken by a state medical licensing authority or a state or national professional society.*

- How will the term “disciplinary action” be defined? Considering that each state has its own medical and professional licensing board and procedures, the lack of uniformity could put some practitioners at a higher risk simply because of the state in which they live or work.
- What constitutes evidence of disciplinary action?
- At what point will the DOJ consider disciplinary action to have been taken? Would the filing of a complaint against the practitioner be sufficient? What if there is a pending investigation? What if an investigation resulted in no findings or action – will that be considered?
- What if the action is overturned after a practitioner appeals?
- Is there a timeframe that will be considered?
- How will the Initiating Official obtain the information regarding a provider’s history or record with a state medical licensing authority or the state or national professional society?
- Is the Initiating Official permitted to undertake a review of the practitioner’s record even if no malpractice claim has been filed against the practitioner?

Finally, Bi-state recommends that DOJ provide clarity on the following issues that cut across all five criteria:

- Is each criteria of equal weight when making a decision?
- Is concern about a single criteria always sufficient to hold an administrative hearing? Or are there situations in which there must be concern about more than one criteria?

Given the wide range of issues for which guidance and clarification is needed, Bi-State requests that the DOJ not proceed directly to publishing a Final Rule on these issues. Rather, we request that DOJ flesh out these five criteria to address the questions raised above, and then re-issue this section of the NPRM for public comment. This will provide Health Centers and Bi-State with an opportunity to provide meaningful comment on how this process will be operationalized – something which is not possible at this time, as no details are available.

B. Nature of Consultation with Secretary of Health and Human Services (HHS)

Section 233(i) of Title 42 states that the final determination to exclude an individual from coverage shall be made by the Attorney General “in consultation with the Secretary” of HHS, and the NPRM echoes this

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provision. Bi-State believes that this consultation requirement is an explicit recognition by Congress that HHS is the subject matter expert in decisions concerning the quality of health care services provided by a health care provider. What HHS says or does not say will likely be influential on, if not dispositive of, the final decision by DOJ.

However, the NPRM fails to describe the form or substance of this consultation. For example, will HHS have an opportunity to comment on issues that DOJ has identified, before an individual is notified of a hearing? Will HHS have an opportunity to respond to information presented during the hearing process? Will HHS be permitted to make recommendations to the Administrative Law judge?

Bi-State recognizes that the statute gives the final authority to make these decisions to DOJ; however, the statute is equally clear that DOJ must consult with HHS during the process. Failure to establish parameters for this consultation could lead to inconsistency in how this consultation occurs across time and individuals. It could also be misinterpreted to mean that DOJ must simply *notify* HHS of its actions, rather than to consult with HHS, as the statute requires.

For these reasons, Bi-State recommends that DOJ expand the NPRM to address the nature of the HHS-DOJ consultation and permit public comment on these proposals.

C. Provide the Individual Provider with an Explanation of the Initiating Official's Determination at the Time of Notification of the Hearing (§15.13(c))

Bi-State is concerned that the notice and hearing process, as currently proposed, will be unnecessarily costly and disruptive to both the practitioner and the Health Center. While §15.13(c) of the NPRM outlines the information that will be included in a notice of hearing, there is no requirement that the DOJ inform the individual of the reasons why he or she has been identified as potentially posing an “unreasonably high degree of risk.” This lack of information is exacerbated by the general lack of clarity around how these determinations will be made, as discussed above.

The costs of discovery at the hearing stage could be greatly reduced if the information considered in making the determination were made available to the provider in advance – both the general standards used for evaluating each criteria (as discussed above), and the specific information about the individual provider. Taking these steps would also make the hearing process more efficient and balanced. For these reasons, Bi-State recommends that DOJ provide the individual provider with an explanation of the reasons behind their initial determination as part of the notice of hearing. We also repeat our request for information about how each of the criteria will be operationalized.

* * *

Thank you for the opportunity to comment on this Interim Final Rule. Please do not hesitate to contact me at (603) 228-2830 extension 112 or via e-mail at tkuening@bistatepca.org if you require any clarification on the comments presented above.

Sincerely,



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