



Elizabeth G. Taylor
Executive Director

Board of Directors

Ann Kappler
Chair
Prudential Financial, Inc.

William B. Schultz
Vice Chair
Zuckerman Spaeder LLP

Miriam Harmatz
Secretary
Florida Health Justice Project

Nick Smirensky, CFA
Treasurer
New York State Health Foundation

L.D. Britt, MD, MPH
Eastern Virginia Medical School

Ian Heath Gershengorn
Jenner & Block

Robert B. Greifinger, MD
John Jay College of
Criminal Justice

John R. Hellow
Hooper, Lundy & Bookman, PC (Ret.)

Michele Johnson
Tennessee Justice Center

Arian M. June
Debevoise & Plimpton LLP

Lourdes A. Rivera
Center for Reproductive Rights

Donald B. Verrilli, Jr.
Munger, Tolles & Olson

Robert N. Weiner
Arnold & Porter, LLP

Ronald L. Wisor, Jr.
Hogan Lovells

Senior Advisor to the Board
Rep. Henry A. Waxman
Waxman Strategies

General Counsel
Marc Fleischaker
Arent Fox, LLP

October 9, 2020

The Hon. Alex Azar, Secretary
U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 713F
Washington, DC 20201

RE: Request for Information on Guidance Documents

Dear Secretary Azar:

The National Health Law Program (NHeLP) has worked to improve health care access and quality through education, advocacy and litigation on behalf of low-income and underserved individuals for over 50 years. We write in response to an undated Request for Information (RFI) posted on the Department's website regarding guidance documents. (See Office of the Secretary, Department of Health and Human Services (HHS), Request for Information on Guidance Documents, <https://www.hhs.gov/guidance/sites/default/files/2020-09/HHS-Guidance-Request-For-Information.pdf>).

The Department seeks input "as to which existing HHS guidance documents should be issued through notice-and-comment rulemaking." The RFI is confusing and raises significant concerns regarding the integrity of HHS' rulemaking and other regulatory processes. It should be withdrawn.

HHS recently published a notice of proposed rulemaking that, if finalized, would establish new procedures for guidance documents, including formal notice and comment for certain guidance documents.¹ NHeLP and numerous other organizations submitted extensive comments on the proposed rule, despite the truncated 30-day comment period.² We incorporate by reference our earlier comments and ask they be included in the administrative record for this RFI.

As we explained in our earlier comments, the Administrative Procedure Act establishes requirements for what regulatory actions should undergo formal notice and comment, and expressly exempts general statements of policy from notice and comment.³ Neither the RFI nor the Proposed Rule on Guidance describe the legal basis for subjecting certain guidance documents to notice and comment. Moreover, HHS provides no information or explanation, either in this RFI or the proposed rule on guidance, on what methodology, criteria, or legal standards it will apply when assessing whether a guidance document should undergo notice and comment. We are therefore unable to offer meaningful comments (a point we also emphasized in comments on the proposed rule).

We are also concerned that HHS posted a RFI on guidance documents while a formal rulemaking on the same issue is currently pending. If HHS needs input on what guidance should undergo notice and comment, it should solicited public input through a RFI before embarking on formal rulemaking. By posting the RFI after the fact, HHS underscores that its proposed rule on guidance was ill-conceived and deeply flawed. In addition, the RFI suggests that imposing notice and comment requirements on guidance documents is a *fait accompli*, notwithstanding the pending rulemaking, as well as legal and other concerns raised by commenters. Failing to duly consider public comments is the very definition of arbitrary and capricious rulemaking.

Finally, we strongly object to the method by which the RFI was posted to an obscure area on the HHS website. By failing to publish the RFI in the Federal Register, HHS deprived interested parties adequate notice to consider and respond.⁴ Even if NHeLP were able to fully respond to the RFI, the short comment period is inadequate to fully identify and review current guidance documents as candidates for notice and comment.

¹ U.S. Dept. of Health and Human Svcs., *Notice of Proposed Rulemaking, Department of Health and Human Services Good Guidance Practices*, RIN 0991–AC17, 85 Fed. Reg. 51396 – 51400 (Aug. 20, 2020), <https://www.govinfo.gov/content/pkg/FR-2020-08-20/pdf/2020-18208.pdf>; U.S. Dept. of Health and Human Svcs., *Notice of Proposed Rule Correction, Department of Health and Human Services Good Guidance Practices*, RIN 0991–AC17, 85 Fed. Reg. 52515 – 52516 (Aug. 26, 2020), <https://www.govinfo.gov/content/pkg/FR-2020-08-26/pdf/2020-18744.pdf>

² See Ltr. From Wayne Turner, Senior Attorney., Nat'l Health L. Program, to Alex Azar II, Sec'y, U.S. Dep't Health & Hum. Servs., *NHeLP comments on HHS Proposed Rule on Guidance* (Sept. 14, 2020), <https://healthlaw.org/resource/nhelp-comments-on-hhs-proposed-rule-on-guidance/>.

³ *Id.* at 4, citing 5 U.S.C. §§ 551(4), 553(b)(3)(A).

⁴ HHS routinely publishes RFIs in the Federal Register. See, e.g., U.S. Dep't Health & Hum. Servs., *Request for Information on Modifying HIPAA Rules To Improve Coordinated Care*, RIN 0945–AA00, 83 Fed. Reg. 64302 – 64310 (Dec. 10, 2018), <https://www.govinfo.gov/content/pkg/FR-2018-12-14/pdf/2018-27162.pdf>. HHS fails to explain why it declined to do so here.



Given these fundamental flaws, we strongly urge HHS to withdraw the RFI. Please feel free to contact me at (202) 289-7661 or turner@healthlaw.org if you have questions.

Yours truly,

A handwritten signature in black ink, appearing to read 'W. Turner', followed by a long horizontal line extending to the right.

Wayne Turner
Senior Attorney

