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August 16, 2019

BY ELECTRONIC COURT FILING

The Honorable Paul A. Engelmayer
United States District Court
Southern District of New York
Thurgood Marshall U.S. Courthouse
40 Foley Square, Room 2201
New York, NY 10007

Re: Defendants' letter response to Plaintiff's joint letter-motion to compel completion of the Administrative Record and this Court's August 16, 2019 Order, No. 1:19-cv-04676-PAE (consolidated with Nos. 1:19-cv-05433-PAE & 1:19-cv-05435-PAE).

Dear Judge Engelmayer:

Defendants Alex M. Azar II, in his official capacity as Secretary of Health and Human Services, and the U.S. Department of Health and Human Services (HHS) respectfully respond to Plaintiffs' joint letter-motion. Defendants produced to Plaintiffs on July 22, 2019, the vast majority of the materials on which HHS relied in promulgating the challenged rule, excluding (1) certain publicly available material cited by HHS in the rulemaking documents and equally available to Plaintiffs and (2) a small set of materials Defendants identified since providing Plaintiffs with the administrative record. Although Defendants maintain this approach was reasonable and in good faith compliance with the Court's Order, Defendants are working diligently to now provide those materials and to address Plaintiffs' concerns. Defendants anticipate doing so by 5 PM on Monday, August 19, 2019, as Plaintiffs have requested and as ordered by the Court.

Courts have noted that "in order to allow for meaningful judicial review, [an] agency must produce an administrative record that delineates the path by which it reached its decision." *Occidental Petroleum Corp. v. SEC*, 873 F.2d 325, 339 (D.C. Cir. 1989). Defendants respectfully submit that they produced the administrative record to Plaintiffs on July 22, 2019, which included documents sufficient to delineate the path by which HHS promulgated *Protecting Statutory Conscience Rights in Health Care: Delegations of Authority*, 84 Fed. Reg. 23,170, 45 C.F.R. Part 88 (May 21, 2019) (2019 Final Rule). Respectfully, several of Plaintiffs' issues relate to materials that they sought help locating in the administrative record, rather than materials that were not included in the administrative record. Defendants do strive to assist Plaintiffs in a collegial fashion, but these issues do not relate to the completeness of the administrative record *per se*.

Publicly available documents. Plaintiffs seek publicly available documents referenced in the 2008 Notice of Proposed Rulemaking (NPRM) and 2008 Final Rule that preceded the 2019 Final Rule. Pl.’s Letter-Motion at 2. The only documents referenced in the 2008 NPRM and the 2008 Final Rule that HHS considered in promulgating the 2019 Final Rule either were included in the materials Defendants produced on July 22, 2019 or are legal sources that are readily available and not typically included in an administrative record—that is, statutes, regulations, legal cases, Executive Orders, citations to the congressional record, and unenacted bills. Plaintiffs do not identify any case law requiring an agency to include such readily available legal sources in an administrative record, and Defendants do not believe they are required to do so, particularly because the sources are already cited in the relevant rulemaking documents. *See Fuentes v. I.N.S.*, 746 F.2d 94, 97 (1st Cir. 1984).

Further, although Plaintiffs do not contest Defendants’ decision not to include in the administrative record publicly available materials referenced in the 2018 Proposed Rule, 83 Fed. Reg. 3,880 (Jan. 26, 2018) and the 2019 Final Rule, to facilitate Plaintiffs’ review of the administrative record, Defendants are nonetheless working hard to prepare a supplement to the administrative record that includes these publicly available materials, with the exception of statutes, regulations, legal cases, Executive Orders, citations to the congressional record, and unenacted bills. Defendants anticipate being able to produce these documents to Plaintiffs no later than 5 PM on Monday, August 19, 2019, and will endeavor to do so sooner.

In the course of pulling together the above materials, Defendants realized that a handful of documents that HHS considered in promulgating the 2019 Final Rule were inadvertently left out of the administrative record Defendants produced on July 22, 2019. These documents consist of (1) materials relating to the United States President’s Emergency Plan for AIDS Relief (PEPFAR) and (2) indices to the public comments submitted on the 2018 NPRM, which counsel for Defendants initially believed was correctly excluded from the administrative record. Defendants anticipate being able to produce these documents to Plaintiffs no later than 5 PM on Monday, August 19, 2019.

Regulatory Impact Analysis Documents. Plaintiffs assert that the 2019 Final Rule “includes a Regulatory Impact Analysis . . . which cites census data and information from HHS’s grant-tracking system not included in the A.R. and not accessible publicly.” Pl.’s Letter-Motion at 2. That is not correct. Defendants have confirmed that all grant-tracking data and Census data that was considered by HHS in promulgating the 2019 Final Rule was included in the administrative record materials produced on July 22, 2019.¹

¹ In response to Plaintiffs’ question about TAGGS and Census data contained in Exhibit 3, the materials relied on for the assertion about State universities receiving between 100 and 2000 awards per year is in the record at 000537821. In response to Plaintiffs’ question about the list of HHS buildings, that material is in the record at 000540141.

Complaints of Discrimination. Plaintiffs also suggest that complaints of discrimination received by HHS's Office of Civil Rights that are referenced in the 2019 Final Rule "do not appear to be included in the administrative record." Pl.'s Letter-Motion at 2-3. That is not correct. HHS included in the administrative record produced on July 22, 2019 all complaints of discrimination that it considered in promulgating the 2019 Final Rule. Moreover, although the APA does not require it, Defendants are voluntarily preparing an index of those complaints to provide to Plaintiffs to facilitate their review. Defendants anticipate completing this index no later than 5 PM on Monday, August 19, 2019.²

Miscellaneous Issues. Plaintiffs also raise several other miscellaneous issues. Plaintiffs state that they could not access the administrative record until July 23, 2019 and that the version of the record sent to Plaintiffs' counsel included corrupt files. Defendants sent the administrative record, contained on a password-protected USB drive, to Plaintiffs by overnight courier on July 22, 2019. Defendants acknowledge that they inadvertently did not provide the password at that time; however, they did so within twenty minutes of Plaintiffs' request for it on July 23, 2019. Similarly, when counsel for Plaintiffs alerted counsel for Defendants that the administrative record contained a small subset of corrupted files, counsel for Defendants responded promptly on July 25, 2019, by providing working versions of those files via email. Defendants believe that the timing of their production of the administrative record complied with Court's Order and was reasonable, particularly given the volume of the record and the technical complexity of assembling it for production.

Plaintiffs also note that the administrative record produced to Plaintiffs is not text-searchable. As counsel for Defendants informed Plaintiffs on July 30, 2019, Defendants do not have a text-searchable version of the administrative record. Defendants are not aware of any obligation to provide an administrative record in a text-searchable format, and, indeed, Plaintiffs did not request that the administrative record be produced to them in any specific format before Defendants produced it. Defendants also note that the software for making files text-searchable is equally available to Plaintiffs as it is to Defendants.

Finally, Plaintiffs at several points in their letter-motion state counsel for Defendants failed to respond to their requests for information. Counsel for Defendants, which consists of a small team of attorneys, have been working hard to gather information to address Plaintiffs' questions regarding the record, as well as the many questions from the plaintiffs in the other cases involving the challenged rule, and to brief the merits in the litigation. The undersigned regrets that these issues have come before the Court but believes that Defendants' efforts described herein should address any legitimate concerns regarding the completeness of the record.

Defendants and their counsel are utilizing all available resources to provide the documents

² Plaintiffs specifically asked about where to locate complaints 14-193604, 15-193782, 15-195665, 16-224756 and 18-292848. Defendants are currently working to identify those complaints within the administrative record and will follow up separately with Plaintiffs to provide Bates numbers.

discussed above to Plaintiffs in these consolidated cases and the plaintiffs in other cases challenging the 2019 Final Rule. Defendants anticipate that they can provide these documents, along with a sworn certification from HHS explaining that the administrative record is complete, no later than 5 PM on Monday, August 16, 2019. Once Defendants have provided these materials to Plaintiffs, they will file a notice with the Court, along with the sworn certification.

We appreciate your Honor's time and attention to this matter.

Sincerely,

/s/ Bradley P. Humphreys
BRADLEY P. HUMPHREYS
Trial Attorney
U.S. Department of Justice, Civil Division