EXHIBIT E



Working together. Saving lives.

700 North 4th Street, Richmond, VA 23219 tel: 804-782-4800 fax: 804-782-4816 www.unos.org

Brian M. Shepard Executive Director & CEO

February 2, 2018

Dr. Charmaine Yoest
Assistant Secretary for Public Affairs and Agency Chief FOIA Officer
U.S. Department of Health and Human Services
Office of the Assistant Secretary for Public Affairs
Room 729H
200 Independence Avenue, S.W.
Washington, DC 20201

Re:

Freedom of Information Act (FOIA)
Appeal FOIA Case Number 18F081

Dear Dr. Yoest,

I am writing to appeal a decision of the Health Resources and Services Administration (HRSA) denying my request under the Freedom of Information Act (FOIA) sent to the agency on January 12, 2018. I specifically requested that the Agency provide:

[c]opies of all responses submitted to the Health Resources and Services Administration (HRSA) in response to the Request for Information for the Organ Procurement and Transplantation Network (OPTN), issued by the Healthcare Systems Bureau on December 1, 2017, with a response deadline of December 23, 2017, including any responses that may have been submitted after the deadline regardless of whether those responses were considered by the government.

A copy of my request is attached as Exhibit 1. The agency was initially unable to locate comments received in response to the Request for Information (RFI). See Exhibit 2, letter dated January 19, 2018. In a revised final response, the agency located 50 pages of responsive documents. However, the HRSA FOIA office withheld all 50 pages in their entirety, citing FOIA exemptions 4 and 5, 5 U.S.C. § 552(b)(4) and (b)(5). See Exhibit 3, letter dated January 29, 2018. According to the agency, "[t]he withheld material consists of statements from prospective offerors." For the reasons described below, the agency's reliance upon these exceptions is misplaced.

By way of background, HRSA published a RFI on December 1, 2017, regarding the reissuance of a contract for the continuation of the Organ Procurement and Transplantation Network (OPTN)(Solicitation Number: 18-250-SOL-00017). See Exhibit 4. The stated purposes of the RFI are "1) to get potential sources' feedback, comments and suggestions on how the procurement requirement may be improved upon, made clearer, or changed for the better, and

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Tara Storch
W. Kennech Wathburn, M.D.

Dr. Charmaine Yoest February 2, 2018 Page 2

2) to request statements of intent from prospective offerors who intend to bid on the upcoming solicitation."

With respect to the claim that these materials are withheld under FOIA Exemption 4 for confidential commercial or financial information of third parties, the government's RFI issued on December 1 specifically states to prospective offerors the following: "Confidentiality. No proprietary, classified, confidential, or sensitive information should be included in your response. The Government reserves the right to use any non-proprietary technical information in any resultant solicitation(s)." (emphasis added). "Exemption 4 authorizes [the] agency to withhold trade secrets and commercial or financial information obtained from a person and privileged or confidential." 45 CFR §5.31(d); 5 USC §552(b)(4). Based on the clear language in the government's notice, no prospective offeror could possess any expectation of privilege or confidentiality in the information submitted to the government. With this very clear direction that no proprietary information should be submitted in responses, any designation by a submitter that their submission is confidential is frivolous. Even if an offeror's response to the RFI contained proprietary information, only the confidential portions that were appropriately designated would be protected by the exemption, and not the offeror's entire response.

The government has also asserted FOIA exemption 5 as a reason to deny disclosure of voluntarily submitted "statements from prospective offerors." As you know, "[e]xemption 5 authorizes [the] agency to withhold inter-agency or intra agency memorandums or letters that would not be available by law to a party other than an agency in litigation with the agency." 45 CFR §5.31(e); 5 USC §552(b)(5). These third party statements submitted without any expectation of confidentiality simply do not constitute deliberations of the agency. The submissions are not letters or memos drafted by anyone within any Government agency. Rather, the submission are responses to an RFI that were authored by non-governmental third parties, and that are explicitly not subject to any notion of confidentiality. Moreover, statements of opinion from the public sent to the government without any expectation of confidentiality are not entitled to any legally recognizable privilege against civil discovery. We ask only for materials that were submitted to the government by third parties - we do not seek any memorandums, letters, or other documents reflecting any deliberations of the agency.

United Network for Organ Sharing (UNOS) is the coalition of transplant hospitals, OPOs, histocompatibility laboratories, patients and related businesses that has served as the OPTN since the OPTN's first authorization in 1986. The OPTN could potentially benefit from the unfiltered feedback voluntarily provided by the public to the government in response to the RFI. The requested materials have already been located; the asserted exemptions from disclosure are inapplicable; and the burden to the government of producing those documents is minimal. Therefore, we renew our request that the government disclose these materials to UNOS.

Respectfully submitted,

General Counsel

Enclosures

Exhibit 1

From:

Jason Livingston

To:

"foia@hrsa.gov"

Subject:

FOIA Request

Date:

Friday, January 12, 2018 2:27:47 PM

Good morning.

We are seeking copies of all responses submitted to the Health Resources and Services Administration (HRSA) in response to the Request for Information for the Organ Procurement and Transplantation Network (OPTN), issued by the Healthcare Systems Bureau on December 1, 2017, with a response deadline of December 23, 2017, including any responses that may have been submitted after the deadline regardless of whether those responses were considered by the government. Responses were due by email to Patrick Mauro at PMauro@hrsa.gov.

We are willing to pay fees for this response, up to \$25.

Kindly provide electronic copies of these materials to me at <u>Jason Livingston@unos.org</u>. Thank you in advance for your timely response to this request.

Best,

Jason

Jason P. Livingston General Counsel



Working together, Saving lives.

Jason Livingston@unos.org office: 804-782-4843

700 North 4th Street, Richmond, VA 23219

www.unos.org









DEPARTMENT OF HEALTH & HUMAN SERVICES

Exhibit 2

FOIA Office Health Resources and Services Administration 5600 Fishers Lane, Rm. 13N82 Rockville, MD 20857 Telephone: 301-443-2865

January 19, 2018

Sent via email
Jason Livingston
UNOS
700 North 4th Street
Richmond, VA 23219
jason.livinsgton@unos.org

Re: Freedom of Information Act (FOIA) Case Number 18F081 Final Response

Dear Mr. Livingston:

This final letter responds to your FOIA request dated January 12, 2018. In summary, you requested copies of all responses submitted to the Health Resources and Services Administration (HRSA) in response to the Request for Information for the Organ Procurement and Transplantation Network (OPTN), issued by the Healthcare Systems Bureau on December 1, 2017, with a response deadline of December 23, 2017, including any responses that may have been submitted after the deadline regardless of whether those responses were considered by the government.

A records search was conducted in the Healthcare Systems Bureau (HSB) and the Office of Acquisitions Management and Policy (OAMP) but no records were located that are responsive to your request. HSB informed our office that no comments were received in response to the notice.

There will be no charges in this instance because the billable costs are less than our threshold of \$25.

While we believe that an adequate search of the appropriate files was conducted for the records you requested, you have the right to appeal this finding that there are no records in HRSA's possession, which would be responsive to your request. You can appeal and preserve your rights under FOIA and give the agency a chance to review and reconsider your request and the agency's decision.

Your appeal must be mailed within 90 days from the date of receipt of this letter, to:

Dr. Charmaine Yoest Assistant Secretary for Public Affairs and Agency Chief FOIA Officer U.S. Department of Health and Human Services Office of the Assistant Secretary for Public Affairs HRSA FOIA- Page 2

Livingston, 18F081 Exhibit 2

Room 729H 200 Independence Avenue, S.W. Washington, DC 20201

Please clearly mark both the envelope and your letter "HRSA Freedom of Information Act Appeal."

If you would like to discuss our response before filing an appeal to attempt to resolve your dispute without going through the appeals process, you may contact HRSA's FOIA Public Liaison for assistance at:

Denise F. Wallace
HRSA FOIA Public Liaison
U.S. Department of Health and Human Services
Health Resources and Services Administration
Freedom of Information Act
5600 Fishers Lane, 13N82
Rockville, MD 20857
Telephone: (301) 443-2865

E-mail: foia@hrsa.gov

If you are unable to resolve your FOIA dispute through our FOIA Public Liaison, the Office of Government Information Services (OGIS), the Federal FOIA Ombudsman's office, offers mediation services to help resolve disputes between FOIA requesters and Federal agencies. The contact information for OGIS is:

Office of Government Information Services National Archives and Records Administration 8601 Adelphi Road+OGIS College Park, MD 20740-6001 Telephone: 202-741-5770

Toll-Free: 1-877-684-6448 E-mail: ogis@nara.gov Fax: 202-741-5769

If you have any questions, please do not hesitate to contact Edmund Towles at 301-443-2865 or at FOIA@hrsa.gov.

Sincerely,

Thomas Flavin

Freedom of Information Act Office

Turner Flavis



DEPARTMENT OF HEALTH & HUMAN SERVICES

Exhibit 3

FOIA Office Health Resources and Services Administration 5600 Fishers Lane, Rm. 13N82 Rockville, MD 20857 Telephone: 301-443-2865

January 29, 2018

Sent via email
Jason Livingston
UNOS
700 North 4th Street
Richmond, VA 23219
jason.livingston@unos.org

Re: Freedom of Information Act (FOIA) Case Number 18F081 Final Response (Revised)

Dear Mr. Livingston:

This final letter responds to your FOIA request dated January 12, 2018. In summary, you requested copies of all responses submitted to the Health Resources and Services Administration (HRSA) in response to the Request for Information for the Organ Procurement and Transplantation Network (OPTN), issued by the Healthcare Systems Bureau on December 1, 2017, with a response deadline of December 23, 2017, including any responses that may have been submitted after the deadline regardless of whether those responses were considered by the government.

On January 19, 2018, this office issued a final response to you advising that no documents had been located responsive to your request, specifically citing that the Healthcare Systems Bureau (HSB) had not received any comments in response to the notice. In your response dated January 19, 2018, you advised that your organization, UNOS, had submitted comments for that period and provided a copy of that communication to reference in the renewed search. In that communication, you indicated that you were not interested in receiving a copy of the comments submitted by UNOS.

Based on the information provided, the Office of Acquisitions Management and Policy (OAMP) conducted a search and located 50 pages of responsive records (excluding comments submitted by UNOS). I have determined to withhold all 50 pages, in their entirety, under FOIA Exemption(s) 4 and 5, 5 U.S.C. § (b)(4) and (b)(5). At this time the procurement period remains open and HRSA has not made a final determination.

Exemption 4 permits the withholding of commercial or financial information that was obtained from a person outside the government and that is privileged or confidential. The withholding of such information is permitted if disclosure is likely to cause substantial competitive harm to the person who submitted the information. The withheld material consists of statements from prospective offerors.

HRSA POIA- Page 2

Livingston, 18F081 Exhibit 3

Exemption 5 of the FOIA exempts from disclosure certain inter- or intra-agency communications protected by the court-recognized privileges, in this case the deliberative process privilege. The deliberative process privilege permits the withholding of documents that reflect institutional deliberations and covers agency records that are "predecisional" to an agency decision and "deliberative" as well. It is intended to promote open and frank discussion among those responsible for making governmental decisions. The withheld material consists of feedback, comments and suggestions relative to the procurement requirement that may be improved upon, made clearer, or changed for the better. The requested material may be used in the promulgation of changes to the procurement process.

There will be no charges in this instance because the billable costs are less than our threshold of \$25.

The U.S. Department of Health and Human Services' (HHS) policy calls for the fullest responsible disclosure consistent with the requirements of administrative necessity and confidentiality which are recognized by the FOIA, 5 U.S.C. § 552 and HHS' Freedom of Information regulations at 45 C.F.R. Part 5.

If you believe that the information withheld should not be exempt from disclosure, or this response constitutes an adverse determination, you may appeal. By filing an appeal, you preserve your rights under FOIA and give the agency a chance to review and reconsider your request and the agency's decision.

Your appeal must be mailed within 90 days from the date of receipt of this letter, to:

Dr. Charmaine Yoest
Assistant Secretary for Public Affairs and Agency Chief FOIA Officer
U.S. Department of Health and Human Services
Office of the Assistant Secretary for Public Affairs
Room 729H
200 Independence Avenue, S.W.
Washington, DC 20201

Please clearly mark both the envelope and your letter "HRSA Freedom of Information Act Appeal."

If you would like to discuss our response before filing an appeal to attempt to resolve your dispute without going through the appeals process, you may contact HRSA's FOIA Public Liaison for assistance at:

Denise F. Wallace HRSA FOIA Public Liaison U.S. Department of Health and Human Services Health Resources and Services Administration Freedom of Information Act 5600 Fishers Lane, 13N82 HRSA FOIA- Page 3

Livingston, 18F081 Exhibit 3

Rockville, MD 20857 Telephone: (301) 443-2865 E-mail: foia@hrsa.gov

If you are unable to resolve your FOIA dispute through our FOIA Public Liaison, the Office of Government Information Services (OGIS), the Federal FOIA Ombudsman's office, offers mediation services to help resolve disputes between FOIA requesters and Federal agencies. The contact information for OGIS is:

Office of Government Information Services National Archives and Records Administration 8601 Adelphi Road-OGIS College Park, MD 20740-6001 Telephone: 202-741-5770

Toll-Free: 1-877-684-6448 E-mail: ogis@nara.gov Fax: 202-741-5769

If you have any questions, please do not hesitate to contact Edmund Towles at 301-443-2865 or at FOIA@hrsa.gov.

Sincerely,

For DFWallace

Thomas Flavin

Freedom of Information Act Office

Exhibit 4 December 1, 2017

Notice Type: Request for Information

Agency/Office:

Department of Health and Human Services (HHS) Health Resources and Services Administration (HRSA)

Location:

Healthcare Systems Bureau (HSB)

Title:

Organ Procurement and Transplantation Network (OPTN)

I. Description:

This is a Request for Information notice. This is NOT a solicitation for proposals, proposal abstracts, or quotations. The purpose of this market research is two fold: 1) to get potential sources' feedback, comments and suggestions on how the procurement requirement may be improved upon, made clearer, or changed for the better, and 2) to request statements of intent from prospective offerors who intend to bid on the upcoming solicitation.

II. Purpose:

The purpose of this requirement is to support the operations and continual improvement of the OPTN. In performing the activities of the OPTN, the Contactor shall allocate and distribute donor organs to individuals waiting for an organ transplant. The allocation of organs is guided by organ allocation policies developed by the OPTN with analytic support provided by the Scientific Registry of Transplant Recipients (SRTR).

The major objectives to be accomplished for this performance period include:

- (1) Support efforts of the OPTN and HRSA to be consistent with the National Organ Transplant Act as amended and the OPTN final rule;
- (2) Support the continued improvement of national organ allocation policies to maximize the benefit of transplantation to those with end-stage organ failure;
- (3) Continuous evaluation and performance improvement of the OPTN to minimize organ wastage and to maximize transplant benefit, patient safety, and system efficiencies;
- (4) Support and increase transparency and efficiency of the OPTN policy development process;
- (5) Support the OPTN in the development and implementation of strategic and operational planning systems;
- (6) Support the ongoing operation and improvement of the OPTN Data System to provide timely, complete, efficient, and accurate information for policy development, research, and organ placement purposes;
- (7) Provide and implement a system for evaluating member compliance with federal regulations, OPTN Bylaws, and policies, to evaluate and improve program performance and to review patient safety;
- (8) Conduct research independently and collaborate on research and other analyses with the SRTR and the transplant community to support increased understanding of organ transplant and donation issues that will improve performance of the national transplant system; and
- (9) Disseminate information for use by patients and their families, physicians, payers, researchers, and other interested stakeholders.

The functions of the OPTN that the Contractor will conduct are as follows:

Exhibit 4 December 1, 2017

(1) Maintaining a national list of individuals in need of one or more organ(s) for transplantation.

(2) Matching organs to individuals on the waiting list.

- (3) Establishing and enforcing membership criteria for member entities.
- (4) Creating policies for the allocation of donated organs consistent with the OPTN final rule.
- (5) Providing and maintaining a twenty-four-hour system to facilitate organ-recipient matching.
- (6) Assisting organ procurement organizations (OPO) in the nationwide distribution of organs.
- (7) Collecting, analyzing, and publishing organ donation and transplantation data.
- (8) Working actively to increase the supply and utilization of donated organs.
- (9) Having infrastructure and facilities to support the OPTN.

III. RESPONSES

The Government is requesting industry assessment of our draft requirements documentation. This information will be used to revise, if necessary, our documentation in support of anticipated solicitations. All responses will be accepted in PDF format via email to Patrick Mauro at PMauro@HRSA.gov no later than 4:00 PM EST on Friday, December 22, 2017. HRSA will allow all interested parties to submit questions in response to this RFI. Questions shall be submitted to Patrick Mauro at PMauro@HRSA.gov no later than 4:00 PM EST on Wednesday, December 13, 2017. HRSA will respond to all questions via amendment to the RFI. HRSA is under no obligation to consider responses to the RFI or questions received after the aforementioned due dates.

Vendors should provide the following information to HRSA:

- A. Feedback for the PWS to ensure industry is clear about the Government's requirements;
- B. Feedback on the documentation to ensure HRSA / HSB is utilizing best practices;
- C. Feedback on the structure of the PWS; and
- D. Potential contract type that will best serve the public's interest.

This notice does not obligate the Government to award a contract or otherwise pay for the information provided in response. The Government reserves the right to use information provided by respondents for any purpose deemed necessary and legally appropriate. Any organization responding to this notice regarding its capability to respond to the future solicitation should ensure that its response is complete and sufficiently detailed to allow the government to determine the organization's qualifications to perform the work. Respondents are advised that the Government is under no obligation to acknowledge receipt of the information received or provide feedback to respondents with respect to any information submitted. After a review of the responses received, a pre-solicitation synopsis and solicitation may be published in Federal Business Opportunities. However, responses to this notice will not be considered adequate responses to a solicitation.

Confidentiality. No proprietary, classified, confidential, or sensitive information should be included in your response. The Government reserves the right to use any non-proprietary technical information in any resultant solicitation(s).